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MANAGING TECHNOLOGICAL CHANGE IN A MILITARY TREATMENT FACILITY: A CASE STUDY OF MEDICAL DIAGNOSTIC IMAGING SUPPORT (MDIS) SYSTEM

by

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December 1994

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Picture archiving and communication system (PACS) represents an enormously expensive technological innovation in digital imaging which has the potential to alter the way in which radiology is practiced. The purpose of this thesis is to provide a better understanding of the requirements for PACS technology and the implementation of information systems in medical facilities. The objective of PACS technology is to improve access to radiographic images and reports throughout medical facilities while decreasing the cost of image production and storage. Medical Diagnostic Imaging Support (MDIS) system is the military tri-service project to install PACS in selected U.S. military medical treatment facilities (MTF) in an attempt to create a totally filmless environment. This thesis includes a case study of the implementation of the MDIS system at Madigan Army Medical Center and the change management issues that surround the introduction of an information system in a health care organization. The issues brought forth in this study are derived from two change models in the implementation of information systems.

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Managing Technological Change In A
Military Treatment Facility: A Case Study of Medical Diagnostic Imaging Support (MDIS) System

by

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ABSTRACT

Picture archiving and communication system (PACS) represents an enormously expensive technological innovation in digital imaging which has the potential to alter the way in which radiology is practiced. The purpose of this thesis is to provide a better understanding of the requirements for PACS technology and the implementation of information systems in medical facilities. The objective of PACS technology is to improve access to radiographic images and reports throughout medical facilities while decreasing the cost of image production and storage. Medical Diagnostic Imaging Support (MDIS) system is the military tri-service project to install PACS in selected U.S. military medical treatment facilities (MTF) in an attempt to create totally filmless environment. This thesis includes a case study of the implementation of the MDIS system at Madigan Army Medical Center and the change management issues that surround the introduction of an information system in a health care organization. The issues brought forth in this study are derived from two change models in the implementation of information systems.

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I. INTRODUCTION

A. BACKGROUND

Because officials project that the United States will devote approximately 15% to 20% of its total gross national product on health care by the year 2000, health care reform has become a major priority for the United States government and the health care industry (Aaron, 1993, p. 418). Health care organizations are striving to introduce cost-containment measures by restructuring their organizations in an attempt to save money. Changes have become a way of life in today's health care organizations. Even the basic health care practice is slowly changing from an emphasis on the treatment of disease to prevention and managed care. These changes have provoked uncertainty in the health care field. With this uncertainty has come a fundamental need for information and the technology to manage this information. Vice Admiral Donald Hagen, the U.S. Navy's Surgeon General, has said:

> We can't just continue to do business as usual. As we reduce in size and manpower, the importance of information management and its related technology will become even more important to the efficiency of Navy medicine. One of the foremost challenges will be to get everyone "comfortable" with the new technology and accessing information. (Hagen, 1994, pp.5-6)

As Admiral Hagen noted, information systems are seen as the catalysts of change in health care organizations.

Several health care executives share Admiral Hagen's viewpoint. A 1990 survey of senior health care executives in the United States and Canada found that 64% judged improved information systems essential for future competitiveness in the health care field (Mann, 1991, p. 37-38). In particular, many health care executives are finding that information systems that are focused on care of patients reduced costs for their organizations. In the January 1993 issue of Journal of the American Medical Association (JAMA), patient-care information systems were shown to cut costs and increase efficiency in hospitals by reducing delays which improves patient care (Busse, 1993, p.2). These patient-care information systems principally encompassed the ancillary services, such as laboratory, radiology, and pharmacy: operation where the greatest savings are believed to occur.

Because radiology services are considered one of the most expensive departments in a hospital setting, the United States military medical services initiated the Medical Diagnostic Imaging Support (MDIS) project. MDIS employs picture archiving and communication system (PACS) technology to create a totally filmless digital radiology department (Cade, 1993, p.1). The MDIS information system will enable radiographic images to be stored, accessed, and displayed across a network. With this capability MDIS will save time and money and improve communication between radiologists and clinicians. Thus with

MDIS, the military hopes to cut the cost of health care by managing images more efficiently.

In this thesis, I will assess the merits and the problems associated with implementing PACS technology in a military treatment facility. In particular, I will analyze a case study of the MDIS system and its implementation at Madigan Army Medical Center (MAMC) from March 1992 to June 1994. The focus of this thesis is on what will bring about successful implementation and subsequent adoption of health care information systems. Using Madigan's experience with MDIS implementation and relating it with theories on implementing technological change, I will identify the key benefits of, the barriers to, and the process of promoting acceptance of technological change within a military treatment facility.

B. RESEARCH QUESTIONS

Management in the 1990s, a book published by Massachusetts Institute of Technology (MIT), concluded that the track record for implementing information systems was poor, and that the benefits from these systems were not being realized because investment was being made in hardware technology and not in managing change (Benjamin, 1993, p. 23). To determine what the breadth and depth of military experience with information systems and how effectively the military is managing change, it is necessary to analyze the implementation of one

particular information system, MDIS, and to seek answers to the following questions from the experiences at Madigan:

1. How can the implementation of an information system in a military medical treatment facility (MTF) be managed effectively?
2. What are the key success factors in implementing new technology?
3. How can resistance to change within a MTF be overcome?
4. What are the costs and benefits involved with implementing picture archiving and communication system technology?

C. METHODOLOGY[1]

1. Case Study for Research Purposes

A decision oriented case study is similar to a mystery story. It leads the reader into forming his or her own opinion based on the events and motivations of the characters the author describes. It answers the "how" and "why" of research questions. A case study investigates contemporary events within its real-life context (Yin, 1988, p.23). It also focuses on situations where there is no control by the researcher over the behavior of the persons or events involved in the case. In this regard, case study research has the advantage of adding observations and direct interviews to an

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[1]The Methodology section of this thesis was modeled after the Methodology section of the Naval Postgraduate School thesis *The Management Issues of Implementing Telecommuting:A Case Study* by Charles Howard Bane, Jr., September 1993.

overview of the historical research in the area to provide a more accurate picture of research subjects' attitudes and behaviors.

Researchers recognize the benefits obtained from case research as being more than an analysis of events; it is also a flexible teaching mechanism. Case studies have often been used as preliminary to other types of research. According to Yin in *Case Study Research Design and Methods*:

> Case studies can be used for several research purposes. For example, there may be exploratory case studies, descriptive case studies, or explanatory case studies. What distinguishes the case study is not the type, but conditions. The conditions consist of: (a) the type of research questions posed, (b) the extent of control an investigator has over actual behavior events, and (c) the degree of focus on contemporary, as opposed to historical, events. (Yin, 1988, p.16)

2. Advantages of Case Studies

Case studies provide a rich description of characteristics of such "real-life events as life processes, organization and management behavior, change, relations, and maturation of industries," (Yin, 1988, p.14). Case study research has a unique strength in its ability to assemble multiple sources of information and present the facts to lead the reader to form an inductive conclusion. "As a research endeavor, the case study contributes uniquely to our knowledge of individual, organizational, social, and political phenomena." (Yin, 1988, p.14)

Personal feelings and opinions, documented through interviews and observations, are a vital source of information in understanding decisions made in any given situation. Attitudes, relationships among personnel, and political influence within the organization, are communicated during the interviews and then expressed by the author in the case study. Consequently, the reader is given a story that is more meaningful and vivid than bald facts and figures. The case study furnishes the reader with the subjective human element which is an integral part of any type of individual or organizational research.

3. Disadvantages of Case Studies

The advantages of case study research also contribute to the difficulty in accepting the case study methodology as a valid research strategy. Feelings expressed and communicated during the interview process often have a variety of meanings, are subject to interpretation, and can therefore bias the researcher's view of the situation: some case study results have been influenced by the researcher's subjectivity. In addition, observations may be unique as to a period in time and non-repeatable. This uniqueness suggests that another researcher would not be able to replicate the entire case study. In addition, case study research does not conform to standard and accepted methods of data analysis. This lack of

common language contributes to the uncertainty of the case study.

Several other drawbacks to the case study method are also apparent to the researcher. Case study preparation is time consuming and documentation is voluminous. In addition, one who favors the quantitative viewpoint may be skeptical of case study research because of the tendency to draw generalizations from the conclusions and apply them to other situations. This, however, is not the intent of case study conclusions:

> Case study conclusions are generalizations to theoretical propositions and not to populations or universes...In this sense a case study does not represent a "sample" and the investigator's goal is to expand and generalize theories (analytic generalization) and not to enumerate frequencies (statistical generalization). (Yin, 1988, p.21)

4. Methodology of Thesis Case Study

The case study for this thesis was written primarily for use as a teaching vehicle. This study focuses on specific management issues in implementing the Medical Diagnostic Imaging Support (MDIS) system at Madigan Army Medical Center, Fort Lewis, Washington, between March 1992 and June 1994. The case study was based on data gathered from a review of written documentation on MDIS, personal interviews with MAMC's radiology department staff and MDIS project managers, and through direct observations of the MDIS system.

Written documentation included a review of the literature on hospital information systems, picture archiving and communication system (PACS) technology, MDIS, and teleradiology subject areas. From these various topics came a vast array of information on past experience and current research in the field of implementing information technology in hospital settings. Sources reviewed for this material include books, periodicals, proceedings, workshop papers, meeting minutes, survey results, and technical manuals. This material was used to support much of the information voiced during interviews with 12 members of the radiology staff at Madigan and with Madigan site coordinators from MDIS Project Office. The literature review also assisted in providing a historical perspective of the last two years of implementation at Madigan and an overview of the MDIS' PACS technology there.

Direct quotations were also used as much as possible to enrich the descriptive quality of the case study and to furnish a greater understanding of the situation. Many of the viewpoints expressed during interviews with medical staff from the emergency room, orthopedics, and the intensive care unit were verified by different surveys of clinical staff at MAMC.

These multiple sources of information provided a wealth of knowledge as to the events involved in the implementation process. The use of various kinds of sources also assisted in limiting the effects of personal bias in the case study. Finally, this case study methodology provided

insight into human behavioral responses and interactions regarding acceptance of the MDIS information system at Madigan.

D. ORGANIZATION OF PAPER

This thesis is composed of six chapters. After the introduction, Chapter II is a review of the history, advantages, and disadvantages of picture archiving and communication systems technology. Chapter III contains an overview of the Medical Diagnostic Imaging System (MDIS) project. Chapter IV describes the case study of the implementation of MDIS at Madigan Army Medical Center (MAMC). Chapter V examines issues related to organizational change theory in implementing hospital information systems with particular attention to the implementation experience at Madigan. The last chapter summarizes the thesis and presents conclusions and recommendations drawn from the case study.

II. PICTURE ARCHIVING AND COMMUNICATION SYSTEM (PACS)

A. INTRODUCTION

Picture archiving and communication system (PACS) is a computerized information system designed to manage the digital acquisition, storage, display, and distribution of diagnostic images and related textual information (Huang, 1992, p.131). PAC systems were expressly designed to support the interpretation and management of imagery and associated data. The objective for using a PACS is to improve day-to-day management of operations while maintaining or improving diagnostic ability in the practice of radiology.

With a PACS, a radiology department can eliminate the use of X-ray film by digitizing an image and storing it on an electronic medium such as an optical disk. Using these digital images the radiologist can display X-ray images and patient information data at multiple locations in a matter of moments, thus saving time, increasing productivity, and improving efficiency.

B. BACKGROUND

Only months after the German physicist Wilhelm Konrad Roentgen discovered the new diagnostic imaging process he called X-ray in 1895, physicians quickly embraced radiographic technology as a diagnostic tool. In the 98 years since

Roentgen, the quality of radiographic imaging has dramatically improved. Today's sophisticated digital radiology systems include computed tomography (or CT scanners) and magnetic resonance imaging (MRI). CT scanners and MRI provide the radiologist with three-dimensional digital images that give a more complete and clearer picture of soft tissue parts and potential abnormalities in comparison to the flat image display of conventional X-rays. Important diagnostic tools for the radiologist, CT and MRI systems, are also considered as profitable investments for health care organizations with nearly 20% of a radiology department's workload involved in using these systems.

Logically, the next step in the evolution of radiology departments and digital imaging technology is PACS technology. PACS is the connecting link between the multiple imaging modalities in radiology. It allows for the acquiring of conventional X-ray images in digital format. PACS also provides an efficient method for the handling of vast amounts of data generated in radiology.

Four advances in diverse fields occurred during the 1980s, leading to the development of the PACS technology. These technologies include (Cawthon, 1994, p.1):

1. Cost-effective computed radiography allowing rapid and easy digital radiographic imaging;
2. High speed display workstations with user-friendly and intuitive interfaces;

3. High speed networks allowing rapid transfer and sharing of large image files among multiple users within a hospital/clinic environment and over long-distance; and

4. Dependable image storage technology with data transfer speeds supporting clinically acceptable access times.

With these advances in technology, many in the field of radiology had begun to visualize a totally digital and filmless radiology department. Thus, in January 1982, the first international conference and workshop on PACS imaging was held at Newport Beach, California. This workshop spawned a large amount of research in PACS technology by the radiology and scientific communities in the United States, Japan, and Europe.

A 1989 survey indicated that approximately fifty PACSs were installed in Japan and about thirty in the United States and Europe (Huang, 1990, p. 635). These systems were varied in their complexity. However, only two PACS projects have attempted to implement a totally filmless hospital radiology department: Hokkaido University Hospital in Japan and MDIS at Madigan Army Medical Center. The Hokkaido University PACS project is probably one of the largest projects undertaken to implement medical information systems. It was funded by the Japanese government and began in 1989. The Hokkaido system was designed and planned in a joint venture between Fuji Medical Systems and Nippon Electronic Corporation (NEC). Implementation for this system (like the MDIS system, which

will be discussed in Chapter III) is currently underway and scheduled for completion sometime in the next few years.

In the United States one of the earliest research PACS projects, known as the Digital Imaging Network Systems (DINS) was funded by the U.S. Army. The DINS project explored the possibilities of filmless imaging in the battlefield environment. DINS was a three-year, $19-million project to install PACS at Georgetown Medical School and the University of Washington. The purpose of this effort was to help define the technical requirements for PACS, to determine whether technology was adequate to support those requirements, and to advance the level of digital imaging technology where possible. This project encouraged improvements in digital medical imaging products and convinced Army medical leadership of the value of PACS in peacetime health care settings (Willis, 1993, p. 367). Thus, this early research project demonstrated favorably the capabilities of PACS technology, and led the Department of Defense's (DoD) military surgeon generals to initiate the MDIS project to develop PACS technology for military treatment facilities.

C. ADVANTAGES

PACS is radically changing the practice of medicine for both radiologists and clinicians. Like previous major technological advances such as MRI, all of the advantages and disadvantages of PACS are not clearly understood. To this

end, I will consider some of the current benefits and problems associated with PACS.

1. Image Access and Management

Improved access to images and reports is one of the prime motivating factors in choosing PACS (NMIC, 1992, p. 3). The most fundamental weakness of the conventional film-based systems is that there is only a single copy of each image. "Sometimes it takes up to half an hour to find an X-ray shot in the library, and if they find it, there is only one copy available," said H. K. Huang, a member of the team that developed the PACS at University of California at Los Angeles (UCLA) (Busse, 1993, p.1). Film accessibility becomes a problem especially in large health care facilities where there are many simultaneous requests for the same image. In one recent survey at a military medical center, 69% of the clinicians stated that film accessibility was the greatest problem in radiology (Leckie, 1009, p.336).

Films are often signed out and, even when signed out are rarely returned to the film room library, as noted below. Even if the hard copy is never removed from the file room, it is often misfiled, mislabeled, or lost in the vastness of the film library. These problems were evident in a survey of film accessibility at Madigan prior to the implementation of MDIS. This survey showed that only 16.5% of the films for inpatient chest X-ray images could be located 8 to 48 hours after being

performed and checked out, and only 38% of non-chest X-ray images were available after a search of the file room library during the same period of time (Leckie, 1993, p.337). When radiology films cannot be found, the diagnostic ability of a radiologist is obviously impaired. At UCLA, it was estimated that 25% of the radiological diagnoses were delayed because films were being used elsewhere or were lost (Busse, 1993, p.1).

With PACS, image accessibility has been demonstrated to reach 99%. Thus, it can be assumed that images are rarely lost or misplaced with PACS. A study of the MDIS system at Madigan found that in over 4000 cases in a randomly selected week in November 1992, more than 98% of the images could be located under their exact heading or a similar title (Leckie, 1993, p.343). Two additional studies at MAMC during the summer of 1993 compared hard copy (film) availability to soft copy (digital) availability. In the first study of 120 chest X-rays, 33% of the hard copy images were unavailable as opposed to only 5% of the soft copy images. The second study, involving 100 barium enema cases, demonstrated a non-availability rate of 38% for hard copy and 4% for soft copy images (Leckie, 1993, p.342). Hence, these studies demonstrate superiority of PACS over film in image management.

The inadequacies of hard copy film management has produced other consequences as well. Frequently, a physician who is unable to locate a film, will simply repeat the X-ray.

These repeats increase the patient's cumulative radiation exposure to say nothing of increased costs. With PACS, a reduction in repeats or retakes of X-rays is often evident. The retake rate at Madigan radiology department decreased from 6.18% prior to MDIS implementation in January, 1991 to 3.80% in January/February 1994. This rate represents approximately a two-fold reduction of repeats as a result of introducing PACS technology into Madigan. Consequently, PACSs are not only beneficial to the radiologist and clinician but to the patient as well.

In general, the distribution and management of images and data are more reliable using a PACS. PACS offers significant advantage over conventional film-based system for image management. As the workload in radiology continues to increase at a projected five percent per year PACS provides a radiology department with the ability to meet the growing needs of health care facilities and improved patient care.

2. Image Quality

Digital techniques have consistently produced images with sufficient detail and diagnostic quality to be acceptable to radiologists at Madigan (NMIC, 1992, p.13). In a comparison study of hard copy versus soft copy image quality for 100,000 images, every clinical finding noted on the hard copy was also evident on the soft copy. In addition, several clinical findings were picked up on the digital soft copy image that

were inconspicuous or absent on the hard copy image (Leckie, 1993, p.345). Hard copy films tend to fade over time once processed; digital image quality does not deteriorate.

Another superior feature of PACS is that it allows electronic image manipulation after capture. Windowing and leveling are two types of image manipulation which permit a radiologist to enhance a poor quality original digital image by finding the optimum digital data set and adjusting the contrast level of image algorithms from the data set. Consequently, images that would have been deemed unacceptable on film can now be salvaged with PACS. Other PACS image manipulation tools include these four: (1) zoom (enlarging a portion of the screen much like using a magnifying glass), (2) flip (turning the image upside down or left to right), (3) inverse video (reversing the negative image to a positive image), and finally (4) mensuration (overlaying calibrated measuring templates).

During his interview an orthopedic surgeon at Madigan reported enthusiastically on the benefits of these image manipulation tools particularly the PACS workstation mensuration tool. This enthusiasm was due in large part to the ease and accuracy in calculating distance and angle. Previously he had had to place a ruler on a film to take these type of measurements. Tools such as these aid both the radiologists in their interpretation and the clinicians in their diagnosis and treatment of patients. Hence, PACS

imaging techniques supply added incentive to utilize the system.

3. Economic Benefits and Productivity

PACS requires a substantial initial investment. Cost estimates for PACS from research and development to full deployment in a typical health care facility is approximately $7 to 10 million (Tighe, 1993, p. 63). In addition, the direct operating costs for a PACS are greater than those of the existing film-based system. In one study, the PACS was 12% to 17% higher in direct cost when compared to a conventional system (Crowe, 1992, p.184). The higher direct operating costs appears to be based on maintenance costs which can be as high as $500,000 annually. On the other hand, maintenance of conventional film-based systems is approximately $16,500 per year. Despite the high price tag, some direct and more substantial indirect savings must also be considered in evaluating an investment in PACS. In particular, use of PACS technology can increase productivity and reduce the length of inpatient time.

The direct savings with regard to PACS is realized in lower film cost, processing, and storage. It is estimated that an average 350-bed hospital spends about $700,000 per year on film and chemicals. Although different types of exams consume differing amounts of supplies, chemicals for processing film images average 15 cents per film sheet, and

the film sheet costs from $0.45 to $1.10. However, the cost of PACS' computed radiographic (CR) technology is only $0.0018 per image. The problem is that, the CR plate reader costs $60,000 to acquire (Gelish, 1992, p.23). The total direct savings from film processing cost depends on a radiology department's workload and how filmless the department plans to become.

Less film storage space is another persuasive incentive for using PACS technology. A 300- to 400-bed hospital requires sufficient storage space to support about one million films for a four year period, which is equivalent to a 5,000 square-foot room for the file library (Gelish, 1992, p.24). In contrast, the same number of films can be stored on one optical disc jukebox (ODJ)[2] that is about the size of a small refrigerator (or about five square feet). However, this is not a direct correlation because space allocated to film file-rooms varies depending on the facility. For example, the file room for the Radiology Department at Wright-Patterson Hospital occupies about 13% (or 2800 square feet) of floor space of the radiology department and contains approximately 4 million films; on the other hand, Bethesda contains 250,000 films located in 3532 square feet. Hence, the direct savings related to file room space is unique to each facility.

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[2] See Appendix A for detail description of optical disc jukebox.

With the reduction in space for film storage, fewer file room personnel will be necessary with a PACS. One study estimates that about 55% of file room staff time could be eliminated through the use of a PACS (Saarinen, 1990, p. 830). This saving is largely due to less time spent by file room personnel searching for films. The time saved by these personnel can be devoted to more productive tasks.

In addition, the productivity for clinicians must also be considered. With PACS, clinicians spend less time performing clerical functions or waiting for images and reports. PACS allows images to be retrieved and displayed within seconds, instead of minutes or hours. The provider need not spend time and energy walking to, from, and around in the file room library in search of images. Saarinen reports that 75 hours per year could be saved with the implementation of PACS (Saarinen, 1990, p.814). In addition, more complete patient information can also be displayed along with images, aiding the clinician in making diagnoses more quickly. Studies by the University of Washington Medical Center (UWMC) showed that radiologists can save at least ten percent of the time they spend reading films by not having to search for them. The UWMC study also showed that about 14% of a radiologist's reading time is interrupted by referring physicians seeking information on their patients or wanting to examine the films themselves. PACS would eliminate half of the time devoted to these consultations by use of this system.

The UWMC study calculated the potential time savings through the use of a PACS to be 10% to 15% for radiologists (Saarinen, 1990, pp. 823-830). With an average annual salary in the Department of Defense (DoD) for contract services being between $150,000 to $250,000 per radiologist per facility, a 10% to 15% saving can translate to between $15,000 to $37,500 per year savings in increased productivity.

Productivity increases are also expected for radiology technicians through the use of PACS. In 1991, the Gastro-Intestinal (GI) section of the Radiology Department at MAMC performed a total of 1986 imaging exams with the assistance of seven radiology technicians (or 284 exams per technician). By 1993 after the GI section became completely filmless utilizing PACS technology, only five technicians were necessary to perform 3333 examinations (or 667 exams per technician) (Leckie, 1994, p.9). Due to a shortage in personnel, the two radiation technicians no longer required in the GI section were switched to positions in Madigan's radiology quality control section. This example demonstrates a two-fold increase in productivity by "doing more, with less" through the use of PACS technology.

An economic analysis proposal for implementation of MDIS at Naval Hospital Bethesda, Maryland, projected a total labor savings would be $113,768 per year (NMIC, 1993, p. 69). However, the productivity savings might not be fully appreciated or understood, since personnel, like the GI

technicians, are usually rotated to other positions or perform other tasks. Thus, an increase in productivity is not seen as reducing personnel and jobs, but rather as an efficient reallocation of personnel and time.

Associated with indirect savings for "length of patient stay," a study conducted by the Department of Radiology at the Ochsner Medical Foundation in New Orleans, Louisiana assessed the economic benefits that could be derived from PACS. The researchers projected a ten percent reduction in length of stay for hospitals performing at least 25,822 radiographic procedures annually with a PACS (NMIC, 1992, pp 50-58). Another recent study estimated that a two percent reduction in average length of stay would cover the expected extra annual costs of digital imaging (NMIC, 1992, p.72). With the assumption that on average one day in the hospital will cost $1,000, this can be translated into a $20- to $100-dollar savings per inpatient visit for the patient and the hospital. However, because length of stay depends on a number of other variables such as severity of illness, real saving is difficult to predict.

Currently, the economic benefits of a PACS are still being identified and analyzed. As mentioned earlier, PACS technology does require a substantial initial investment, investment costs should decrease as PACS technology improves and more vendors move into this field. The benefits of PACS cannot be assessed by using direct costs alone as shown by the

above studies. An appreciation for the indirect savings of using a PAC system should also be considered. Increasing productivity and reducing length of stay are also pertinent factors in evaluating the economic benefits of PACS especially in light of managed health care.

4. Teaching and Research Support

With a PACS, instructors from different residency programs have access to a variety of images and related diagnostic reports from which to instruct. This variety allows for interesting cases to be grouped together in files within the PACS database for retrieval as educational material. With this material, residents and clinicians can view and learn to recognize rare abnormalities in radiology images. This factor along with multiple, simultaneous access to images, can enhance training and educational opportunities in medical training hospitals, like Madigan.

Additionally, research is greatly simplified and improved by the rapid access capabilities of PACS, which allows researchers to scan an entire collection of radiological images in a relatively short time to identify particular cases relevant to their research. Thus, more medical research can be performed without exhaustive file room searches, and greater access to data improves the validity of the researcher's conclusions.

5. Staff Morale

PACS is changing the fundamental role of radiology within health care organizations, through promoting increased cooperation among radiologists, referring clinicians, and administrative staff. With PACS, the radiologist is given a better link to the clinician and can provide a better quality of service. The use of a PACS can foster greater cooperation among various departments in the hospital and emphasize the value of radiological expertise and service as a complementary specialty. In this regard, most clinicians and radiologists perceived PACS as being beneficial to their overall organization. This perception was noted in a survey of the medical staff at Madigan in which 98% of the respondents favored the MDIS system (Leckie, 1993,p.346). PACS offers the radiology staff fewer interruptions to contend with and fewer interactions with frustrated clinicians searching for films. PACS improves the morale of the radiology staff which increases the satisfaction of other clinicians and the patients.

In addition, the use of state-of-the-art technology in a military teaching hospital should attract talented physicians to military service (NMIC, 1992, p.19). Radiology residents and staff physicians may be less likely to leave military service if they are provided with PACS. Because of the shortage of radiologists, DoD has had to hire non-military radiologists at sites like Key West, Florida, and Oak Harbor,

Washington, at a cost of $200,000 per year. The use of state-of-the-art technology such as PACS will be beneficial in recruiting qualified personnel. A resident at Madigan mentioned in his interview how impressed he was with MDIS and how instrumental it was in his decision to enter Madigan's radiology residency program.

6. Quality of Care

Acceptance of any new technology including PACS depends on how health care providers perceive the resultant affect quality of patient care. As a general rule the quality of patient care is very important to physicians. With PACS, patients benefit from more accurate and rapid interpretation of examinations, availability of comparison images, speedier distribution of reports, improved consultations in the diagnosis of their cases, and less repeat exposure to radiation. The MDIS Project Office has reported that, nationwide, 30% of images are read by physicians other than radiologists, which leads to the occasional misinterpretation of radiological exams (NMIC, 1992, p.20). With PACS, images are automatically routed and reviewed by a board-certified radiologist or a subspecialist within a particular field of radiology. Diagnostic reports are then forwarded, along with the corresponding images, to the referring physician for review. Clinicians in different departments or different facilities can access the same image simultaneously, making

consultation easier and more effective. This whole process increases better communication in the treatment of patients and focuses on providing better patient care.

D. DISADVANTAGES

There are inherent risks and disadvantages in implementing any new technology. If users are satisfied with the existing operations, they will be reluctant to recognize the potential benefits of PACS. Currently, the radiological community in this regard is taking a "wait and see" approach towards PACS technology (Crowe, 1992, p.181). Despite radiologists' "wait and see" attitude toward PACS, they are not happy with the conventional film-based system for image management. However, radiologists do not yet seem ready to replace the conventional film-based system with PACS. The problem arises when radiologists, who read a lot of images in a day, believe that they cannot view digital X-rays as rapidly as film. Consequently, a radiologist would rather remain with the conventional film-based system. In addition, PACS technology must address characteristics such as ease of use, responsiveness, consistency, dependability, and availability of support mechanisms in order to overcome barriers to change.

1. User Reluctance

The primary advantage of a film-based system is its familiarity. In general, radiologists are trained to read X-ray films on a light box. They are comfortable with

reading films from this medium in a batch processing mode at the beginning and end of the day. It is the radiology technician's responsibility to spend hours systematically setting up the film images on the light box to await the radiologist's review. With this prior preparation, a radiologist can read and interpret films in this manner in about one to two seconds per image. PACS has the potential to change this type of operation to a real time on-line process. This process would require the radiologist to perform the retrieving and setting up of images on the screen display. This change in the radiologist's operation to a real time process would demand a shifting of, or refocusing on, how radiologists are taught to interpret radiographic images. Understandably, radiologists are not particularly enthusiastic about this change of operation to a more real time basis.

They may be reluctant also to accept a PACS, because the system has the potential to reduce the number of radiologists needed in the delivery of care. As technology improves, an artificial intelligence system could be developed that would read and interpret radiological images. Use of an artificial intelligence system implies that fewer radiologists would be required. In addition, teleradiology with its ability to send radiological images over commercial communication lines is also expected to reduce the need in the future for radiologists because images could be read and interpreted at centralized locations. Other members of the

radiology staff, such as radiology technicians and file room clerks, are also concerned about being reassigned or losing their jobs in the transition to a PACS environment. All of these factors, have created some fear and resistance in the radiology community. However, this resistance to PACS can be minimized if the clinical benefits and incentives of the system are made readily apparent.

2. Reliability

A high level of reliability is critical to the success of a PACS; that is, users must have access to medical images even in the event of a system failure. With PACS, system maintenance and operational reliability are crucial to radiologists because of their reliance on the technology to supply images for reading and interpreting. On the other hand, a conventional film-based system requires little maintenance expense, for example, simply replacing a bulb on the light box in order to read film X-rays. The maintenance costs for a MDIS are approximately $500,000 annually. Currently this cost is included under the contract's warranty during the initial installation of the system. As the system matures, this maintenance cost is expected to rise to an annual cost as mentioned above of approximately $500,000.

Without operational reliability and back up procedures for the image data, radiologists will reject PACS technology. However, the reliability of the MDIS operation at Madigan

demonstrated in the first ten months was 98.8%. To achieve this, MDIS employs fault-tolerant architecture and operational redundancies to minimize the frequency of system failures and to ensure that no single point of failure can cause major disruption to radiology services. In addition, daily data backups are performed while the MDIS system is running. The major cause of down time for MDIS at Madigan was related to problems with the hospital-wide air-conditioning system and not with the MDIS system. Excluding problems related to air-conditioning, this system was operational 99.7% during the first two years of the implementation process (Smith, 1994, p.7). Presently, the radiologists at Madigan are very confident in the reliability of the MDIS system.

To support high reliability, a plan for preventive maintenance should also be considered. This maintenance plan should have a sufficient number of qualified support personnel available to ensure the proper functioning of the PACS. At the MDIS system sites this support is furnished by in-house vendor personnel with varied backgrounds and jobs. These personnel include a system engineer, a database and archive manager, and a computer technician and trainer. These personnel are permanently staffed at each facility after implementation of the system. The system engineer is responsible for the optimal operation of all the computer components of the MDIS system, including the database, interfaces, electronic image archives, and transmission.

The database manager is responsible for all aspects of image archiving. He or she assures that imagery is entered into the archive in the correct format and is readily available for physician review. The computer technician or trainer is responsible for maintenance and the training of others in the use of the components of the system. He or she also should be proficient in troubleshooting techniques and in the operation of each component of the system. All these support personnel contribute to the transition process of going from film to MDIS. PACS, like any new technology, must be properly maintained to insure its reliability.

E. CONCLUSION

The purpose of the assessment of the advantages and disadvantages of PACS is to establish the need for this type of technology. Given concerns about the acceptability of PACS, it is unlikely that radiologists will change from the existing conventional film-based system to PACS until a clear demonstration of its costs and benefits is provided (Crowe, 1992, p.181).

The necessity for integrated PACS is obvious from a study showing the increased availability of images and the improvement of management. The whole process of medical image acquisition and manipulation is moving in the direction of digital technology. PACS is essential for expeditious hospital management, communication, and archiving of images.

PACS serves as a powerful tool for better health care delivery and for facilitating research and teaching. According to Dr. Huang, "the implementation of PACS technology is inevitable for the future of radiology" (Huang, 1990, p.639).

III. THE MEDICAL DIAGNOSTIC IMAGING SUPPORT (MDIS) PROJECT

A. INTRODUCTION

The Medical Diagnostic Imaging Support (MDIS) system is an implementation of Picture Archive and Communications System (PACS) into the clinical environment. The MDIS system allows for the development of a filmless or near-filmless radiology department in facilities of varying size from clinics through large tertiary care medical centers. The goal of the MDIS program is to eliminate 90% of the film used in a military treatment facility (MTF) within two years of installation (Smith, 1994, p.2).

B. BACKGROUND

The U.S. Army, Air Force, and Navy Surgeons General jointly established the MDIS project to oversee the introduction of filmless medical imaging capabilities throughout the military health care system. Four major sites were selected in 1990 for this project: Madigan Army Hospital, Fort Lewis, Washington; Brooke Army Medical Center, Fort Sam Houston, Texas; Wright-Patterson Air Force Base, Dayton, Ohio; and Luke Davis-Monthan Air Force Hospital, Phoenix, Arizona (Radiological Society, 1991, p.138).

Prior to this selection, the military services assembled a team of experts for the MDIS system project. This team,

comprised of a core group of individuals with various educational background and work experience, included engineers, contracting specialists, administrative and financial experts, two practicing radiologists, a systems engineer/analyst, a radiology physicist, and experts in communications, medical maintenance, radiological technology and radiology information systems. The team traveled around the United States visiting different PACS research and development sites. The result in 1989 was the MDIS technical performance requirements document, which was part of the request for proposal (RFP) in the solicitation process for the MDIS contract (Cawthon, 1994, p.2).

In the fall of 1991, the MDIS system's $225 million dollar contract was awarded to a joint venture between Loral Western Development Laboratories and Siemens Medical Systems. The selection of the contractor was based on clinical performance, price, and value of their system (NMIC, 1992, p.2). One element in the success of the MDIS contract was the establishment of the MDIS Project Management Office. This office houses a team of individuals dedicated to the successful installation and implementation of the MDIS system at each of the original sites. The team oversees the contractor compliance and directs site preparation, installation, and acceptance testing of the MDIS system at all sites, and facilitates contact between the sites and the vendor. Implementation of MDIS is proceeding in a phased,

unit-modular approach, with completion including all testing and training expected by 1995.

C. SYSTEM OVERVIEW (Appendix A)

While the Loral/Siemens MDIS system is a proprietary system, it employs an open system architecture which is scalable to any size facility and can be expanded and upgraded as digital imaging technology evolves. Presently, the MDIS system at Madigan includes computed radiography (CR) for all plain radiographs except mammography, a 40 gigabyte Working Storage Unit (WSU), a 100-platter (1 tetrabyte) Optical Disk Jukebox (ODJ), and 25 workstations. Each of these components is organized into one of the four primary subsystems. The Image Acquisition Subsystem provides the images that are stored and viewed with MDIS. The Image Database Subsystem is the central database, image file server, archival image storage area, and interface for patient demographic data. The Image Display Subsystem provides both hard copy and soft copy viewing of MDIS exams reports. The Communication Network Subsystem ties all the MDIS elements together and provides for high-speed image transfer. Each subsystem is connected to the Working Storage Unit (WSU) which is the heart of MDIS. Thus, MDIS system architecture is linked in a modified star topology (Figure 1). In order to have a better understanding of a MDIS system, we shall look at each subsystem in more detail.

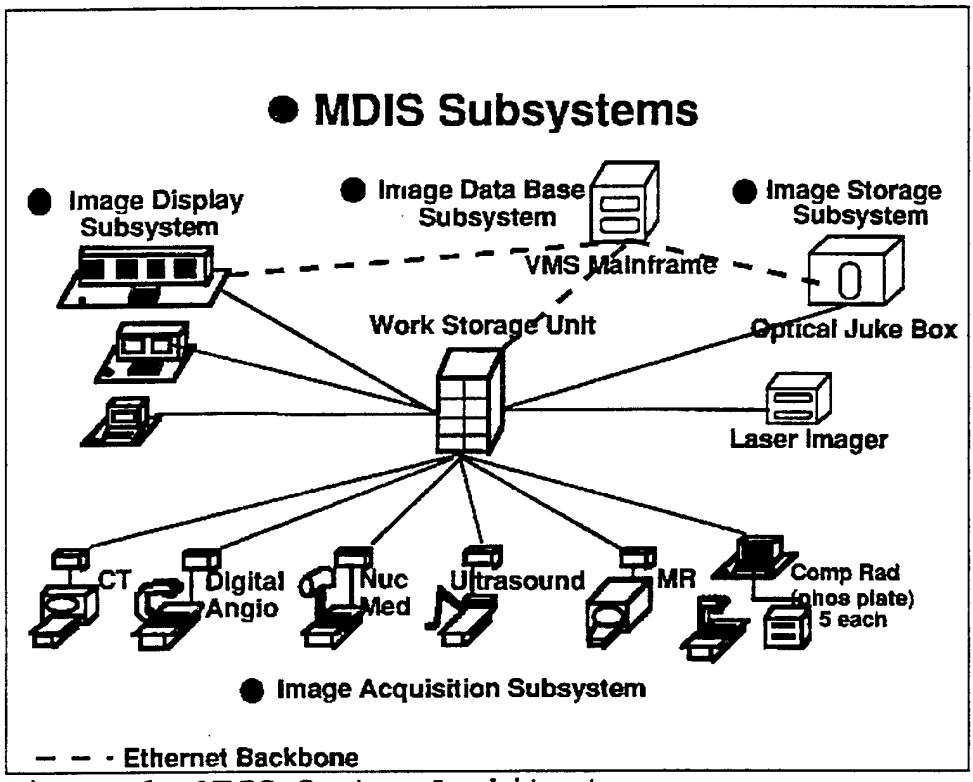

Figure 1: MDIS System Architecture

1. Image Acquisition

Nearly 80% of examinations in a typical diagnostic radiology department are now digitally formatted (Nemat, 1990, p.14). The MDIS system must interface with other digital radiology equipment in order to acquire digital radiological images. The MDIS system supports several different digital imaging modalities including computed tomography (CT) scanners, magnetic resonance imaging (MRI) scanners, ultrasound, computed radiography (CR) units, and film digitizers. Because of these multiple imaging modalities, a significant problem with MDIS is the lack of standardization

of interface protocols among these different types of imaging equipment.

Standardization of medical images and equipment was begun in 1985 by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA), which published a digital imaging and communications standard (ACR-NEMA). The main objective of the standard was to promote interoperability among imaging devices and imaging management systems. The ACR-NEMA standard covered protocol definition for the physical, data link, and transport/network layers corresponding to the open system interconnection (OSI) standard reference model. Although ACR-NEMA standards are a beginning, many areas remain where compliance is vague and at times incomplete. Therefore, even when two vendors produced "ACR-NEMA compliant" equipment, they were not easily connected. A practical example of this incompatibility occurs at MAMC with the MRI interface to the MDIS system. The General Electric (GE) MRI system cannot communicate with the Loral/Siemens MDIS system. Both vendors are at an impasse as to who will modify their interface to make it compatible with the other, since these manufacturers do not want to divulge proprietary trade secrets. The MDIS system is not alone in having to overcome this type of interface problem. This situation is becoming more commonplace as radiology departments integrate and expand their operations with multiple-vendor equipment.

The newest ACR-NEMA initiative for standardization is DICOM (Digital Imaging and Communications in Medicine). This protocol has removed many ambiguities and is more complete than previous standards. However, different digital formats can still be selected within the DICOM standard. This problem of obtaining interoperability through use of standardizations plagues the software industry in general, but for PACS this is important if PACS is to flourish and proliferate in a multiple-vendor radiological image equipment environment. The military services along with other PACS operators are calling for more definitive standards from the ACR-NEMA and medical equipment industry to achieve this interoperability.

For the MDIS system, conventional X-ray images are generated using computed radiography (CR) technology. This type of technology exhibits several different characteristics from that produced with film-based systems. For example, computed radiography is a much more forgiving technique because it allows for a wide set of radiation exposures without under- or over-exposing the plate. Its wider dynamic range is at a minimum ten bits per pixel, and spatial resolution is between 2.5 to 5.0 lines pairs per millimeter (Cawthon, 1994, p.4). Consequently, an over- or under-exposed CR plate will still give an excellent image. Because over- or under-exposing radiological images are the two major reasons for technical errors in X-ray production, fewer retakes are necessary. At Wright-Patterson Air Force Hospital, 5% of the

films taken must be repeated, and 28% of these repeats are due to over- or under-exposure. This means that on average 330 films must be retaken per month at Wright-Patterson (Donnelly, 1992, p. 505). Retakes represent a large amount of rework that would not be necessary with PACS technology.

Computed radiography also employs reusable phosphor-plate radiographic system to convert conventional analog X-ray images to a digital format. These CR phosphor plates are 8x10 rather than the normal 14x17 inch film plate and achieve better spatial resolution in image quality. To process these plates, a CR reader is used to recover the image and input it to the system. On average these phosphor plates can be reprocessed as many as 90,000 times at a cost of about $800 per plate. One disadvantage with a phosphor plate is that the image stored on these plates decays over time, so if the CR reader should malfunction then it is possible that the image could be lost. Although these plates can store the image for up to several hours prior to processing, redundance in CR readers is highly recommended. Once the image is processed, it can be electronically stored, manipulated, transmitted, and displayed on a workstation for interpretation without any loss in image quality. Based on the above factors, CR technology has added advantages in imaging quality and cost compared to a film-based system.

2. Image Database

At the heart of the MDIS system is the Working Storage Unit (WSU) which functions as the short-term storage device. Originally developed and utilized for U.S. military reconnaissance but now modified for medical applications, the WSU uses a redundant array of inexpensive disks (RAID) with 40 disks operating in parallel. With RAID, images obtained within the previous 10 to 12 days are available and can be quickly retrieved on the WSU. Images are stored in the WSU with approximately 2.5:1 reversible or lossless compression, giving an effective storage of more than 10,000 CR images. Lossless compression preserves the diagnostic quality of the image data while still reducing the size of the image data file. After retrieval and decompression from the WSU, a CR image takes approximately four to five seconds before it is displayed.

Another storage device working in combination with the WSU is the optical disk jukebox (ODJ). ODJ is commonly used for long-term storage of data records on its multiple optical disks. An optical disk jukebox provides one tetrabyte of long-term storage which is equivalent to one million images. The retrieval of historical images from the long-term optical archive is a critical issue for the success of any PACS. Image retrieval (or fetching) time from the ODJ to the workstation is more variable than with WSU. If the number of images being fetched is as small as four or five, the average

time is about two minutes. If many images are being fetched at the same time, the average time rises dramatically to approximately 20 minutes, too slow for practical diagnostic work.

For both long- and short-term storage, the use of data compression becomes of paramount importance to the performance of MDIS. An efficient compression scheme can drastically reduce storage requirements and transmission times associated with the communication of digital medical images. When data compression applications are motivated by the need to reduce storage requirements, lossless techniques can be employed, allowing perfect reconstruction of the original data from its compressed form. Reasonable compression ratio options range from 2:1 to 10:1. However, image compression in PACS is still controversial because of the possibility of error in the recovery of the image. In some PACS designs compression is not utilized; however, the MDIS system has demonstrated that image diagnostic quality can be preserved with lossless compression techniques at a 10:1 ratio and still provide for optimum storage capability.

3. Image Display

The workstation is a critical component in MDIS, representing the system interface between the system and the user. MDIS utilizes two types of imaging workstations: "diagnostic" and "clinical." Diagnostic workstations are four

high-resolution monitors with at least 2,048 x 2,048 pixel displays (Figure 2). These workstations are used primarily by the radiologist for diagnostic reading and interpretation, whereas clinical workstations have a lower resolution of 1,024 x 1,024 pixel displayed on two monitors for use by referring clinicians for review. The difference in workstations for radiologists and clinicians arises from the demand for diagnostic details which is not as critical for the clinicians as it is for the radiologist.

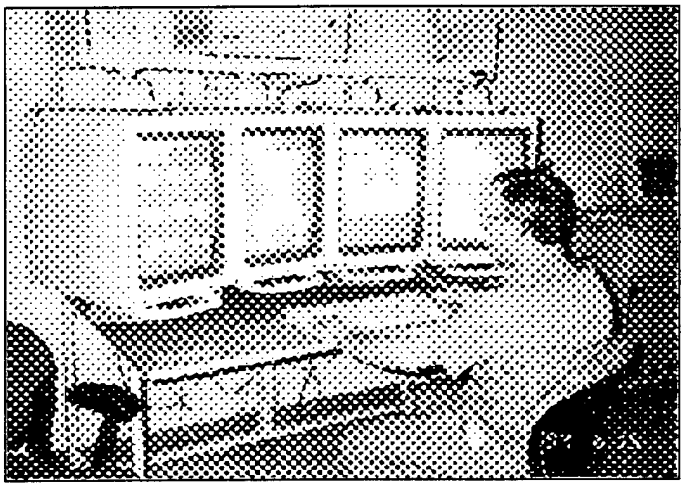

Figure 2: MDIS Workstation

The basic platform for the workstation is the Apple Macintosh computer. The Macintosh-based interface is user friendly. The quality of the MDIS interface, or how the user

interacts with the system, strongly affects the ease with which users can make the transition from a film-based system to MDIS. An excellent interface can persuade reluctant users to accept the system whereas a poor interface can discourage even the most enthusiastic and devoted user. Physicians, who are usually computer illiterate, find that the Macintosh system aids in their acceptance of MDIS (Leckie, 1993. p.338). Icons and pull-down menus, which can be selected at the click of the mouse, simplify use of the display workstation for non-computer literate individuals. "Quick keys" are also available for commonly used functions so an experienced user can move through the functions more rapidly.

One drawback to the Macintosh workstation is the headings for the icons and menus which are very small, sometimes making them difficult to read. In addition, it is also very easy to lose sight of the mouse cursor on the workstation display. Notwithstanding these difficulties, the ease of use of the Macintosh workstation has had a direct effect on the ease of training. Of the clinicians, 77% have learned to use the basic functions of the workstation without any previous computer training (Leckie, 1993, p.341).

4. Communication Network

Communication entails physical and logical methods of transferring digital images, patient data, and diagnostic reports from one point to another, whether internal as in a

medical treatment facility, or external as in a teleradiology operation. Rapid display of images is of primary concern in the design of MDIS. The Communication Network Subsystem has a Fiber Distributed Data Interface (FDDI) backbone. This FDDI backbone allows for a data transfer rate of 100 megabits per second. Another key feature is the connection between the workstation, database, and WSU. The workstation queries the database via a high-speed Ethernet fiber-optic line. The database provides the workstation with the necessary information and access rights to retrieve image data from the WSU. The WSU transmits images to the workstation via a direct fiber-optic link.

D. TRAINING

Training is a vitally important part of the implementation of MDIS. Although the MDIS workstation is user friendly, hands-on training for all users is important. If users do not feel completely comfortable with the workstation, they will not use it. The basic reason for a phased implementation plan was to accommodate gradual introduction of the technology, not only throughout the Radiology department, but throughout the hospital and clinic structure of the medical centers undergoing the initial implementations of MDIS. With turnover of both civilian and military personnel in general relatively high at Madigan, the ease of training contributes significantly to the advancement of the system's

implementation process. Training on the MDIS system is very intuitive. An average of ten minutes was required by most clinicians to learn to use the workstation through informal instruction from other colleagues. However, the MDIS contractor is responsible for any initial or refresher training and training any personnel on new software upgrades as part of the contract.

A training plan was initiated to assist in the formal education of the Madigan staff. This plan was provided by the MDIS contractor, using a professionally trained group of personnel who developed the schedule and instructional materials. The training plan included the initial establishment of training standards which detailed the individual tasks to be learned and the proficiency level which an individual must demonstrate. In addition, the training was performed in either a group or one-on-one. Group training was the more common practice with size restricted to no more than 18 students per group. Each student was trained in certain particular tasks, depending on their function, under the direct tutelage of the instructor. For example, in the training of radiology technicians they were taught the most diverse subjects of any student group. They gained knowledge of each assigned imaging modality which would transmit images to the MDIS network, the theory of computed radiology image formation and printing parameters, image quality control activities, the archival process, and maintenance training on

computed radiography readers and processors, film digitizers and network laser printers. After this initial training, many of the radiology technicians demonstrated such proficiency that they were instructing the contractor personnel, according to Dr. J. Carter, the radiation physicist at Madigan. Training for MDIS has continued to accelerate at MAMC, as the staff has become familiar with the system, and newcomers now have ubiquitous help from other users throughout the facility.

IV. CASE STUDY: IMPLEMENTATION OF MDIS AT MADIGAN ARMY MEDICAL CENTER

Madigan Army Medical Center (MAMC) is a new 416-bed tertiary care military treatment facility situated in Tacoma, Washington. It is also one of the Army's major teaching hospitals with a medical staff of nearly 500 physicians who represent most of the medical subspecialities. The medical staff sees roughly one million outpatient visits per year, and the radiology department with a staff of 12 radiologists and 18 residents performs over 160,000 radiological exams per year. Consequently, Madigan was selected by the Army's top medical leadership as the first site to implement the Medical Diagnostic Imaging Support (MDIS) system. Colonel Sankara Babu, head of the Radiology department at Madigan, recalls the first time he heard about the MDIS project:

> It was at a conference in Washington, D.C. in 1990. The Surgeon General of the Army gave a speech in which he said that MAMC's radiology department would be the first to implement the new MDIS technology and that Madigan would be totally filmless within two years.

However, the MDIS contract was not awarded until the fall of 1991, and implementation began at Madigan in March 1992. The MDIS contract called for a 30-month implementation of hardware and software with the installation performed in phases.

Even though MAMC was a new facility, the original architectural design for the Radiology department underwent

changes to accompany the new PACS equipment. Primarily, this involved expanding ventilation, heating, and air conditioning capacities. The reduction in image filing space required under MDIS made possible modification to the original plans allowing construction of a computer room out of floor space originally allocated to the file room library. Some of the additional file room space was also converted into added office space for residents. Additionally in the first six months, implementation consisted of installing hardware equipment in the computer room, running fiber-optic cabling, and placing workstations throughout the facility.

When the doors were open at the new Madigan hospital, MDIS was up and running as far as conventional X-ray was concerned. As of June 1994, MAMC is still only about 50% filmless. Delays have resulted from interface and software problems between the MDIS and other radiographic equipment. Other areas of the department now on-line with MDIS are the Gastro-Intestinal (GI) and Computed Tomography (CT) sections. Full implementation of all radiographic equipment at MAMC is expected to be completed by the end of 1994.

Even with the delays in full implementation, the MDIS project continues to receive top leadership support and attention. This leadership commitment has earned MDIS the reputation of being a very top-down-driven system. From the radiologists' standpoint, MDIS is not really perceived as a grass-roots effort. Rather, the MDIS system was mandated by

the U.S. Army Surgeon General to be implemented at Madigan in order to contain costs and to become the prototype for a totally filmless radiology department. LT Colonel Fred Goeringer, director for the MDIS Project Office said,

> After several cost analyses, the military decided PACS could save them money in the long haul by improving the hospital's productivity and film management. It is not a new modality, it's a productivity, quality improver. We're very interested in cost and savings (Tighe, 1993, p.67).

MDIS is the Army's answer to cutting the cost of radiology services. In addition, the Army top leadership sees PACS technology and teleradiology as a step in the wave of the future towards telemedicine.

The U.S. Army has devoted a considerable amount of time and money to the success of the MDIS project at Madigan in its search for totally filmless environment in radiology. The Army is also counting on MDIS to help eliminate the time and distance problems plaguing its management of medical images. The Army's leadership is keenly aware that many are watching the MDIS project at Madigan to see if it will succeed or fail. According to Captain Robert DeTreville at the MDIS Project Office, the Army has currently invested some $20 million dollars in MDIS and approximately $8.6 million alone has gone for the implementation of the MDIS system at Madigan.

Contrarily, Colonel Babu sees MDIS as being "a high-tech solution to a low-tech problem" of image management in radiology and believes that the expectations for MDIS are too

grandiose. He does not concur with the MDIS vision espoused by the Army medical leadership. His perceptions are that PACS technology is too futuristic. He would rather have seen the money devoted to MDIS go into providing additional clerical and support personnel to the Army's radiology departments.

Many of the radiology staff at MAMC also believed that the merits of MDIS have been overestimated by top leadership. However, one radiologist, a proponent of the system at Madigan is Major Donald Smith. Major Smith has worked on the MDIS project since its inception. He was actively involved in the initial team established by the Army to look at PACS technology, and he assisted in developing the technical requirement specifications for the MDIS system. In addition, he has also written extensively on MDIS and PACS technology. As an expert in the field, Smith fully advocates the necessity of picture archiving and communication systems (PACS) technology as the future of radiology.

Smith has devoted his full time to the implementation of the MDIS system at MAMC. As the MDIS champion at Madigan, he is attempting to sell the system to the radiology staff. He hopes to change the outlook of many radiologists from the conventional use of light boxes to digital viewing of radiological images.

In Smith's opinion, MDIS at Madigan has become a model of successful implementation of PACS technology. He believes the selection of two very reputable vendors went a long way

towards ensuring the success of MDIS. Loral, noted for its work in military reconnaissance, and Siemens, with a reputation as a leader in reliable and sophisticated diagnostic radiology equipment, have encouraged the acceptance of the MDIS system at Madigan. Both Loral and Siemens have invested ten years and close to $100 million in development of the technology. They have a fundamental commitment to PACS technology. Fred Prior, a representative for Siemens on the MDIS project, stated:

> It really is a high-priced poker game. MDIS is a must-win for Siemens. If PACS is going to succeed it's because of MDIS. If MDIS doesn't happen, PACS won't happen in this decade. If you're going to be in the PACS business, MDIS was the biggest game in town (Tighe, 993, p.60).

Another key factor in Smith's view was the work of the MDIS Project Office. The MDIS Project Office has been instrumental in creating a team of experts, including radiologists, to oversee and support the installation of MDIS at each site. The Project Officer has directly involved clinicians and radiologists in the decision making process for every aspect of the MDIS project. He has encouraged a closer working relationship with the site users. However, the distance from Ft. Detrick, Maryland, to Madigan, Washington, has hampered travel and direct involvement in the day-to-day operation between the MDIS Project Office and the radiology staff at Madigan.

As a consequence, Major Smith was assigned the primary function of acting as an intermediary or communication link among the radiology staff at MAMC, the MDIS contractor, and the MDIS Project Office. At weekly meetings with the radiology staff, he listens to complaints and recommendations, attempts to answers any questions, and passes along any new updates. These meetings are also a forum for the airing of the advantages and disadvantage of the MDIS system from the radiology staff's viewpoint. At these meetings, Smith and the other proponents of the MDIS system among the radiology staff point out the tangible benefits thus far experienced at Madigan, while those opposed to MDIS list the shortcomings of the MDIS system. Many of the arguments on both sides are often supported by evidence from surveys performed by the radiology residents and other radiology department staff members.

In Smith's viewpoint, the greatest benefit of MDIS system has been in the improvements with image management. Of major importance was the improved accessibility to radiological images that MDIS provided. One survey conducted by the radiology staff at Madigan found that 98% of the radiological images were available and accessible on the MDIS system (Leckie, 1993, p.343). For conventional hard copy images, only 16.5% of the films could be located within 48 hours after being performed, and only 38% of the films were available after an extensive search of the film library at Madigan

before the MDIS system was implemented (Leckie, 1993, p.337). In addition, this improved image accessibility had also another less tangible advantage of protecting the radiology staff from having to deal with frustrated clinicians looking for X-ray films or reports. Now the clinician can look on the MDIS system to see the image he wants and if the report has been completed. While Colonel Babu admits the need for better image management, he is not convinced that PACS technology is yet at a point that it can replace the film-based system. He believes that improved image management could also have been achieved by the use of a computerized database tracking system for films at less cost than MDIS.

At a cost of $8.6 million, MDIS is an expensive investment for image management system. However, Smith maintains that this up front cost will come down as PACS technology improves. After the success of the initial MDIS implementation at Madigan, he believes that MDIS will save money in the long run by reducing film processing and storage cost, utilizing of resources more efficiently, and increasing productivity. He mentioned the fact that the need for less film room storage space has already resulted in providing the radiology department with space for resident offices. In addition, the GI section of the radiology department after the implementation of MDIS system has experienced an increase in productivity. This section went from 284 exams per radiology technicians annually to 667 exams per technicians annually.

Thus, the department was able to reduce the technician staff size in the GI section from seven to five. Two of the technicians were switched to positions in the department's quality control section.

Babu disagrees with Smith's comments on these economic benefits. He holds that the economic benefits of the MDIS system are not substantiated. The Radiology Department will always have to maintain a film library for those images like mammography that MDIS cannot support and for patients at other facilities that do not have PACS technology but whose records are maintained at Madigan. Labor savings are also not being realized as an economic benefit. None of the clerical staff positions have been eliminated in the film library or the department, and the two radiology technicians from the GI section were switched to the quality control section because of the added burden placed on that section by the new MDIS system requirements. In addition, with both hard copy film images and soft copy MDIS images being concurrently produced for all radiological exams at Madigan, direct savings from reduction in film processing has not materialized. Conventional film-based systems cost approximately 60 cents to $1.25 which includes film sheet and chemicals while MDIS costs $0.0018 per image. The Radiology department is thus incurring both these costs. The cost of this duplication has added to the cost of operating the department. Babu also alludes to the fact that this difference in costs does not take into

consideration the high maintenance cost ($500,000 per year) or initial investment in computed radiographic equipment which the MDIS system requires.

This parallel system of hard copy and soft copy processing is being conducted as a comparison of image quality. Smith claims that MDIS's soft copy digital image is comparable to hard copy image. He backs this statement with a study at Madigan comparing image quality for 100,000 images which found that in no cases was the clinical finding on the hard copy not noted on the soft copy. The study also showed that several clinical findings were picked up on the soft copy image that were inconspicuous or absent on the hard copy (Leckie, 1993, p. 345).

Babu counters Smith's statement with the fact that soft copy imaging is not possible with mammographies because the digital technology is not detailed enough to pick up small lesions. Where film provides 4,000 x 4,000 pixel image, MDIS can only provide 2,000 x 2,000 pixel for a diagnostic image.

Babu also asserts that MDIS system workstation requires low luminescence to properly view the image display. Hence, the workstation must not be in a lighted room or placed next to a light view box; otherwise, the quality of the image is hampered. For significant details, the MDIS workstation imaging enhancement tools must be used by the radiologist. Using these tools takes time; thus, MDIS slows the radiologist. If these tools are not used by the radiologist

and the radiologist misses a soft tissue abnormality, what are the legal ramifications for the radiologist with MDIS? There is no current answer for this question; thus the radiologist has both a soft copy and hard copy image to review if he or she chooses.

Both sides argue their viewpoints on the merits and deficiencies of the MDIS strongly. Some of the radiology staff feel that Smith tends to gloss over problems with MDIS, and he is more interested in the technology than in their opinions. As one staff radiologist stated, "In his enthusiasm for MDIS, Smith tends to oversell the system." Many radiology residents are reluctant to criticize MDIS around Smith for fear of receiving a lengthy lecture on the benefits of the system; however, they recognize the MDIS system benefits and appreciate Smith's dedication.

Because of perceived lack of objectivity and the increasing amount of time Smith has spent working on MDIS, another staff radiologist, Major Robert Leckie, was selected to assist Smith with the MDIS implementation. Leckie is well respected by his peers in the Radiology department. Despite his involvement in the MDIS project, he has remained actively involved in the day-to-day functioning of the department. Leckie sees MDIS' real success as depending on clinical acceptance by users of the system. His initial experience has confirmed this belief. Leckie points out that users are more likely to adopt the new system enthusiastically if it is

simple to use and understand. His focus has been gaining acceptance for MDIS from the clinicians and radiologists.

Clinical acceptance of the MDIS has differed between clinicians and radiologists. Both groups have benefited from increased accessibility and availability of images, but the primary reason for the differences in acceptance is workload. In this regard, MDIS slows down the radiologist. When MDIS was installed in 1992, the first image of an exam was displayed in 8-12 seconds, too slow to meet the clinical demands of the radiologist (Cawthon, 1994, p.18). Images are now routinely displayed in four to five seconds. However, a radiologist can still read images faster in two seconds on a pre-set light box than he can by viewing the images on a MDIS workstation. Consequently, the radiologist has no real motivation to use MDIS. Rather, the incentive comes from an altruistic concern to provide better quality service to the clinicians. Dr. Stiggelbout, the oldest staff radiologist at MAMC who has been practicing since 1956, stated, "We need to stick with the MDIS system because it benefits the clinicians."

Age and experience in working with computer systems does not seem to inhibit the radiology staff's acceptance of the MDIS system. Even Stiggelbout, who had not used a computer before working with the MDIS workstation, is enthusiastic about the system. In fact, he uses the MDIS workstation more than the rest of the radiology staff.

Stiggelbout appreciates the ability of MDIS to give him real time images as soon as they come off the computed radiography (CR) reader. While other radiologists continue to read images in batch mode, Stiggelbout has shifted his practice to providing clinicians with reports in less than one minute turnaround. Stiggelbout believes that implementing this new type of technology requires restructuring of how radiology is currently practiced. MDIS requires a more real time reporting protocol to get the greatest benefit from its potential.

Other clinicians are not as concerned with the rapid display of images. Rather, availability of images on workstations outside the Radiology department is considered important by these physicians and what they perceive as its greatest benefit. By a conservative estimate, MDIS saves the clinician one hour per week through faster image and report availability (Smith, 1994, p.13). One study projected that a total of 75 hours per year could be saved with MDIS system (Saarinen, 1990, p. 814) This is a great time-saver for clinicians and is a major incentive in their utilization of MDIS.

This acceptability of the MDIS system by referring physicians has remained extremely high throughout the implementation process. For instance, in a survey of 58 clinicians in the winter of 1992-93, 98% stated the workstation significantly improves patient care and 100%

stated the workstation saved them time (Leckie, 1994, p.8). These views continue to persist throughout the medical staff. The major complaint of clinicians is that some do not yet have a workstation in their area.

The initial implementation at MAMC provided only nine workstations (six in Radiology and three in other clinical sites). By the end of 1994, there will be 118 workstations throughout MAMC (Figure 3). Smith points out that it was important to establish clearly the number and location of workstations in the early stages of the project in order to provide rapid availability to the user. To accomplish this, the Madigan MDIS Project Site Managers met with each department within the hospital to discuss their clinicians' preference in workstation locations. The clinicians were asked the maximum number of physicians working in their clinic at any given time and the percentage of time they spent looking at radiographic images. The number of workstations needed in each clinic was determined from these data. In some situations additional workstations were added because of logistical problems with the departmental layout and to the low-luminescence of the monitors which required them to be placed in a separate dark location away from normal operations. An example of this additional requirement for workstations occurred in the emergency room (ER) where one terminal was located in a side room in which the overhead lighting could be turned off and another terminal monitor was

February 1993	February 1994	By End of 1994
ICU	ICU	Additional clinics and wards
ER	ER(4)	
Orthopedics	Orthopedics(7)	
Radiology (6)	Radiology (6)	
	Pulmonary/Surgery	Total 118
	Pediatrics	
Total 9	Family Practice	
	Internal Medicine	
	Surgery ward	
	Medical ward	
	Neonatal Intensive Care	
	Total 25	

Figure 3: Number and Location of Workstations at Madigan

placed at the central ER desk. However, even though the workstations are available currently in only a limited number of locations, many of the residents and staff at Madigan commented that the first place they look for a radiological exam is on MDIS. Many have quickly come to appreciate that the system is more reliable than the conventional film-based system in assuring the rapid access and availability of their images.

One of the MDIS workstations at MAMC is located in the intensive care unit (ICU). The ICU clinicians now regularly review both the immediate (or STAT) and routine examinations on this workstation. With the film-based system the ICU physician was required to walk to the Radiology department to find the film, and to waste 30 minutes or more. In many cases

clinicians were not able to review films until hours later because they could not leave the ICU. With MDIS, the images can now be reviewed routinely less than 15 minutes after the image has been taken (Cawthon, 1994, p.17). This has meant that errant tube and line placements in a patient are detected and corrected much faster. Additionally, quicker availability of images has confirmed the placement of feeding tubes and allowed nutritional supplements to be started sooner. Thus, MDIS has resulted in a better quality of care that the ICU clinicians can provide to their patients (Cawthon, 1994, p.17).

Another type of clinician who has come to appreciate the MDIS system is the orthopedic surgeon. Orthopedic surgeons generally rely heavily on radiographic images in their clinical practice. At first they were opposed to MDIS; now they are strongly supportive. All the orthopedic surgeons interviewed preferred MDIS to the conventional film-based system. Each of the surgeons in the clinic stated that he had saved one to two hours per day from the old system in locating images and reports. In addition, the repeat rate due to poor image quality has decreased because CR technology allows better visualization of bony structures through casts than film-based systems. Fewer retakes were also necessary for follow-up of scoliosis cases because of the ability of MDIS to enhance and manipulate the image on the workstation. In addition, the measuring of angles and distances by use of the

workstation enhancement tools has contributed to more exact evaluation of orthopedic conditions such as scoliosis than has hard copy film. According to Major J. Pitcher, head of the Orthopedic residency program at Madigan, another benefit to orthopedics was significant improvement MDIS gave to the their teaching program with its image enhancement tools, the creation of prosthetic templates developed to demonstrate replacement angle and position, and archival files of interesting cases. Finally with MDIS, an emergency room physician can now consult the orthopedic surgeon about a patient's fracture without the surgeon's leaving his busy clinic (Leckie, 1994, p.9). Orthopedic surgeons were so taken with MDIS that they were requesting that workstations be placed in the operating rooms for use during surgery.

While radiologists have been slower in their acceptance of MDIS, in general they perceive the benefits to clinicians and have begun to welcome this new technology. Numerous lessons have been learned in the first two years of operation of the MDIS system at MAMC. The implementation of MDIS has had its technical and leadership problems. In fact, there are still many issues that need to be addressed, such as ambient lighting difficulties when using low-luminescence monitors, interface compatibility problems with other radiology equipment, and the slowness of image display. However, these are minor and technical in comparison to major acceptance by the users of this system, which has been its greatest success

factor. Users must be able to buy into the system. Changes continue to take place in the department, and the implementation of MDIS system at Madigan persists.

V. THE CHANGE ISSUE

A. INTRODUCTION

Implementation is the entire process of organizational change surrounding the introduction of a new information system. Implementation of information system research has not as yet found a single explanation for system success or failure. How can one determine if the implementation of an information system is successful or not? The answer lies with various criteria that have been developed to measure system success (Laudon, 1988, pp. 609-613):

1. High level of system use;
2. User satisfaction;
3. Favorable attitudes of the users towards the information system;
4. Economic incentive.

As the case study demonstrates, the implementation of MDIS at Madigan was considered a success. This success was measured by the favorable attitude and acceptance of both clinicians and the radiologists towards the MDIS information system and their utilization of it in their day-to-day operations. In order to analyze this success and some of the key success factors in implementing information technology in a health

care setting, we will review Madigan's experience with the implementation of the MDIS system in relation to theories models from a research of the literature for adopting information technology.

B. LITERATURE REVIEW

The impact of introducing information systems into an organization has generally been studied from a variety of theoretical perspectives. Several characteristics have been cited by researchers as possible factors influencing the successful implementation process; these include user participation, management commitment, system complexity, communication, experience with the technology, education, and attitudes of affected personnel (Laudon, 1988, pp. 610-626). Such factors are largely behavioral and change issues. Consequently, researchers are approaching the implementation of information systems in organizations from a human perceptive of managing change such as sociotechnical approach. Many information technology researchers have drawn from the change management literature to create theoretical change process models for the successful implementation of information systems: for example, the two models used in the comparison to the MDIS implementation at Madigan below in the Change Model Section.

Research models are also adapted from theories related to the "diffusion of innovations" (Hebert, 1994, p. 372). These

models are a theoretical basis for examining the underlying forces influencing the adoption of information systems. In a field study Moore and Benbasat examined innovation diffusion theory in the context of end-user computing. They perceived the influence of subjective norms, attitudes, and perceived voluntariness on the adoption of technological innovation (Moore & Benbasat, 1990).

In a 1983 study, E. M. Rogers consolidated the results of over 3,000 empirical studies and identified five perceived reasons for adopting new innovations: relative advantage, compatibility, complexity, trialability, and observability (Roger, 1983). He noted the importance of communication and interpersonal influences as vital organizational factors in the success of implementation process. He also theorized that adoption of any new innovation is dependent on worker perceptions of the technology and that acceptability toward the technology will depend on his or her attitude. Tornatsky and Klein also claimed that relative advantage, ease of use, and compatibility are consistently the most prominent reasons influencing the adoption of innovation (Tornatsky & Klein, 1982, p. 45).

Beath and Ives noted that a system champion is crucial for implementing information technology (Sprague & McNurlin, 1993, p.507). Bria also emphasizes the necessity of a physician champion for health care information systems (Bria, 1992). In particular, he claimed that this was the most significant

factor in the acceptance and successful implementation of a patient care information system at El Camino Hospital (Bria, 1992, pp. 5-10).

From the vast amount of research on management in organizational change and diffusion of innovations with regard to information system, I have selected only two of the most recent theoretical models for the implementation of information system in an organization. I will use these models to compare and contrast with Madigan's experience with implementation of the MDIS system. The first model is from Robert Benjamin and Eliot Levinson's "A Framework for Managing IT-Enabled Change" in the summer 1993 issue of *Sloan Management Review*. The second change model is by Marilynne Hebert's "Adopting Information Technology in Hospitals: The Relationship between Attitudes/Expectations and Behavior" in *Hospital and Health Service Administration* fall 1994. The authors claim that their models provide a basic framework for the successful implementation of information technology systems into an organizational environment. Their models were developed from a compilation of change management literature, innovation diffusion theories, and their own personal experience or research findings in the implementation of information systems.

C. CHANGE MODEL

1. Benjamin and Levinson: Eight Principle Framework for Managing Information Technology Enabled Change

Robert Benjamin, research associate at MIT's Sloan School of Management Center for Information Systems, and Eliot Levinson, senior consultant in information systems, suggested that the acquisition of new information systems alone is not sufficient to increase productivity. They advocate change to realize the benefits of this type of technology and to enable the successful implementation of the system. Their premise shows technology, business processes, and the organization must be adapted to each other in order for information systems to be successful. Benjamin and Levinson identified eight principles in their framework for managing the implementation of information technology that need to be followed in adopting particular aspects of information systems (Benjamin & Levinson, 1993, p.26). Only by following these eight principles, Benjamin and Levinson concluded, can the benefits of investing in technology be fully realized.

a. Development Of A Systematic Process For Change

Benjamin and Levinson considered a systematic process as a road map that provides a common frame of reference and vocabulary when discussing issues involved in the implementation process. At an initial glance, in their explanation of this principle, the systematic process appears

to be a stepwise approach for the installation of the information system. An example of this systematic process would be the process model and program schedule the contractor, Loral/Siemens, developed for the MDIS system at Madigan (Appendix B).

However, Benjamin and Levinson broadened their perception and explanation of this systematic process. They saw the process as leading to a vision which provides a common purpose and direction from the present to the future state of the organization. In this regard, the systematic process for MDIS implementation began with the Army Surgeon General creating a vision with the objective of implementing a totally filmless medical imaging environment. This process continued in a progressive fashion in an effort to bring this vision to fruition.

The first step the Army took was in the initiation of extensive early research in investigating the potential benefits of PACS technology. This early research was known as the Army's Digital Imaging Network Systems (DINS) project. This project encouraged improvements in PACS digital medical imaging products. It further convinced the Army's medical leadership to take the next step which established the MDIS project. The MDIS project began with the creation of a team of experts to develop the technical specification requirement for the MDIS system (Appendix A). This team included radiologists and other clinicians, and involved them from the

start in the acquisition and decision making process for the project. This action incorporates a very important aspect of change management: user participation.

User participation in the design and implementation of information systems has several positive results. First, if users are heavily involved in the system design, they have more opportunities to mold the system according to their requirements. Second, they are more likely to react positively to the system because they feel that they control or have an investment in the system. Experiments and field studies have supported these results that user participation: challenges the users, fosters commitment to change process, and develops the skills and knowledge to handle change. From the outset, the medical staff's opinions and participation should be solicited when implementing health care information systems. Bria also emphasized this point of getting the physicians involved so that they are a part of the information system development and implementation process (Bria, 1992, p. 20).

The next step in the formation of the systemic process was the establishment of a centralized MDIS Project Office for the project. It was responsible for coordinating efforts to implement PACS technology into military treatment facilities and for soliciting input from the users. In addition the MDIS Project Office oversaw the acquisition, installation, and implementation at each site. To facilitate

the success of the MDIS implementation, Madigan Army Medical Center, the Army's newest tertiary care facility, was selected to be the first site to implement MDIS. Major Donald Smith, a radiologist who had been on MDIS' team of experts, was assigned the role as MDIS system champion at Madigan. He was also given the responsibilities to stimulate awareness of PACS technology and the benefits it had to offer six months prior to implementation at Madigan. Finally, goals for the full implementation were set for completion in two years at Madigan. In actual practice, the implementation process has been slowed and the goal of completion in two years has not been achieved. In 1994 50% of Madigan's Radiology department was filmless. The vision remains and considerable time and effort is expended in pursuit of full implementation of MDIS at Madigan.

Borrowing from their analogy, Benjamin and Levinson fail to develop and mention that roadblocks will occur on the road map. Not everyone will agree with the vision or the systematic process in implementing change. As an example, Colonel S. Babu was skeptical about the ability to achieve a totally filmless radiology department. He did not agree with the MDIS vision the Army medical leadership espoused. In addition, he held a position of power and influence as head of the Radiology department. Thus, Babu was a major potential roadblock in the successful implementation of MDIS at Madigan.

The reason for Babu's opposition to the MDIS system was a result of his feeling that the system was thrust upon him with little or no input given by him in the process. This is a recurring theme in studies of implementation and change management. His lack of acceptance of the MDIS system could have had a profound effect on the radiology staff's use of the system. However, his opposition was not an influence over the remaining radiology staff.

What overcame this roadblock? The answer lies in communication among the radiology staff. The weekly radiology staff meetings on the MDIS implementation furnished a forum for the voicing of all viewpoints. It provided Smith and Leckie, the system champions, with opportunities to dispel Babu's criticism of the MDIS vision. In addition, the benefits of PACS technology were logically supported in the department by research and surveys done on comparison of image availability and quality between hard copy film and soft copy MDIS images. The radiology staff was also persuaded by the clinicians' opinion of MDIS as being beneficial for their patients and a time saver for them. Even with the lack of perceived objectivity by Smith, a proponent of the system, the results of the surveys aided in confirming the advantages of MDIS over a film system. Benjamin and Levinson, in this first principle, should have shown both the need to develop a systematic process and the need to develop a dialog between the stakeholders in order to avoid a detour in the process.

b. Manage Equilibrium And Mutual Adaptation Of Organization, Technology and Business Process

Benjamin and Levinson tend to be rather vague in their explanation of this second principle. Equilibrium they equate to maintaining the balance in an organization, and that change brings an organization from one state of equilibrium to another. They see the change manager's responsibility to understand how the organization will change and what actions and resources are necessary to reestablish the equilibrium for the organization (Benjamin, 1993, p.27). They suggest that the change managers should focus on what must change in the relationship of the organization, technology, and process in adapting to change.

Benjamin and Levinson are not clear in who these change managers are or how one identifies them in an organization. Rather, they argue that changes in technology, organization, and process are mutually dependent on each other. This is very similar to other organizational change theories, like Pasmore's *Designing Effective Organization*. Pasmore suggested a sociotechnical approach to information system implementation. Sociotechnical approach aims to blend technical efficiency with sensitivity to organizational politics and human social needs. He emphasized user participation in the implementation process. Pasmore also identifies the change managers as those stakeholders who are aware of the need for change. This need provides the

stakeholder with a way to overcome the inertial force inhibiting change.

Although some resistance is to be expected, Benjamin and Levinson perceive most of the resistance as normal and rational. Resistance occurs when stakeholders are comfortable with the status quo, when they do not understand why the change is desirable, and when they have doubts about the organization's ability to achieve the desired change (Benjamin, 1993, p.29). Through training, communication, and commitment of resources by the organization, Benjamin and Levinson feel that commitment for change can be achieved. Researchers have grouped user resistance into categories (Laudon, 1988, p.623):

1. People-oriented;
2. Systems-oriented;
3. People-system interaction.

People-oriented users reason that resistance to information systems is attributed to factors inherent in people or groups within the organization. Strategies for avoiding this type of resistance include training and education and user involvement. In a health care organization there is a tremendous range of experience and training with information systems. That is why it is essential that a training plan be developed that will be flexible enough to handle this variety of requirements when introducing a new information system into a health care organization. For MDIS,

this training plan was furnished as part of the contract. However, ancillary services personnel, such as those in the Radiology department at Madigan, are much more computer literate than other health care professionals, due in part to the highly sophisticated and computerized equipment these services have come to rely on. Rather than entertaining a phobia towards computers, ancillary service personnel tend to embrace the new state-of-the-art technology. Even with experience, all users should still receive a thorough training in the system's operations and capabilities. While education tends to be very time-consuming, the learning curve for an MDIS system was relatively short.

Education also assisted in communicating the reasons for implementing MDIS and the benefits of PACS technology throughout Madigan. At Madigan group training was used to provide this necessary background and understanding of the MDIS system. Group training refers to a classroom setting involving four or more students per instructor. The advantages of group training are:

1. It allows students to learn in the company of their peers.

2. It ensures the efficient use of time by the training personnel.

3. It provides a consistent message.

The disadvantages of group training are:

1. Not all persons in a group will learn the techniques at the same rate.

2. It is difficult to call a consistent group of users together for training.

3. This method ignores the busy time schedule in health care organization.

In addition to education, peer pressure instituted by the system champion is another effective means of dealing with resistance. Resistance can be overcome through understanding the system's capabilities and encouraging utilization of the system. Thus acceptance of the system and utilization can be achieved among the users.

System-oriented users object to features of the information system. To overcome this problem system design should be user friendly, or the user should be involved in the design of the system features. MDIS is a user-friendly, easy, and responsive information system. These characteristics have contributed to the ease with which the clinicians have adapted to the implementation and overcome much of their resistance of the clinicians' daily use of the system. MDIS has many other characteristics that facilitated its acceptance by the physician. MDIS enhanced the speed with which physicians can go about their daily work, and the image display quality has been demonstrated to be as adequate for diagnostic interpretation as hard copy film image in comparative studies at Madigan. In addition the Macintosh interface was a great advantage in minimizing the learning curve for the physicians. With a simple 20 minutes of instruction, clinicians were able to operate the system to obtain the information they needed.

One other major drawback in the system design from the radiologist's standpoint of MDIS technology is the speed of image display. Radiologist want images to be displayed in two seconds or less. If this speed is not reached, then full implementation and acceptance by the radiology staff is rather doubtful. The new software for faster retrieval of images from the long term storage and the increase processing card the contractor is attempting to initiate will speed up the display time. As the case study pointed out, Loral/Siemens has invested heavily in the success of MDIS and they are trying to be responsive to the demands of the users in adapting the technology to the organization, a response Benjamin and Levinson advocated in this principle.

Finally, people-system interaction is the way the system and the organization blend. This interaction has to do with the structure, communication, and collaboration within the organization. For avoiding this type of resistance, an organization needs open communications and good relations between the users and top level management. MDIS Project Office had the role of maintaining the open lines of communications among the radiology staff at Madigan, top Army medical leadership, and the contractor. The only item that hampered these personnel in their effort toward this goal was the distance factor between Madigan and the site and where the other stakeholders were located.

MDIS is also having an effect on the organizational structure and practice of radiology at Madigan. Dr. Stigglebout, as mentioned in the case study, has shifted his practice to a real time mode of operation rather than a batch process commonly used by the radiologist. This real time operation offers the clinician faster turnaround time for radiology reports over the batch mode. However, acceptance of this type of real time processing of radiological images is evolving slower than the adaption to using the new PACS technology. Radiologists do not yet perceive the advantages to themselves in adapting to a real time process in their organization.

c. Determine Whether There Is Enough Energy For Change

Benjamin and Levinson's definition of energy in this context is a commitment on the part of the stakeholders for the change to occur. They believe that an assessment must be performed to test the organizational readiness to support change. The MDIS project does enjoy the total commitment of the Army's top medical leadership and dedication of personnel working in the MDIS Project Office. Even with the delays in the full implementation of MDIS at Madigan, the Army has continued to allocate money and manpower to the success of MDIS implementation process. The Army medical leadership hopes to recoup the initial investment in MDIS by increasing productivity and improving image management; however, as Babu

points out in the case study the money might have gone to a simpler solution for improving image management by hiring additional clerical and support personnel for the radiology departments. The Army medical leadership has a lot at stake with MDIS and is acutely aware of the high visibility this project has in the medical community.

Another heavy investor with a strong commitment to MDIS is the contractor, Loral/Siemens. Loral/Siemens has accepted the risks and challenges of developing PACS technology and the implementation of that technology at Madigan. They believe that the implementation of MDIS at Madigan represents the future and they are committed to being a part of that future.

The Army's incentive in the MDIS implementation at Madigan as stated by Lieutenant Colonel Goeringer in the case study was for cost-containment by improving productivity through better image management. In contrast, the incentive for the clinicians was more towards saving time than reducing cost as a result of the improved image availability and image quality. The incentives of information technology systems that encourage change and the acceptance of change are:

1. It must meet a deeply felt need of a large group of potential users.

2. It must be capable of performing a function better than existing technology.

3. It must be available at the same cost or less cost than existing systems or products.

d. Analyze The Size Of The Change Effort

The method of system implementation should be customized to the particular organization. However, Benjamin and Levinson offer only two types, or what the author calls "sizes," of change: either a "paradigm shift or an incremental change" in their framework. They do not provide a criterion for determining the characteristics for each; rather, the determination seems to be a more subjective judgment. They imply that the incremental change is more common and easier to implement than paradigm shift. This incremental change corresponds closely to the common methodology of a phased or turn-key approach for the implementation of information systems. A phased implementation approach means an introduction into one section or area in the facility at a time. The MDIS project utilized this type of phased implementation for its installation. The primary advantage of this method is a more gradual change in day-to-day operations and an easier transition for departments and personnel. The disadvantages are duplication of effort and increased risk of rejection of the system through inertia by end-users. With MDIS at Madigan Army Medical Center (MAMC), both hard copy films and soft copy digital images are being produced as the transition continues to full implementation of filmless PACS environment. This duplication of effort has added to the cost of the implementation process for Madigan, but it has

facilitated a comparison of the image quality of hard copy versus soft copy.

Along with the use of a phased approach to the MDIS implementation process, the ease of use of the Macintosh interface has also contributed to amount of change that users must undergo. With 77% of the medical staff able to learn the interface on their own or from colleagues, the transition to utilization of MDIS has spread rapidly throughout Madigan making the change effort simpler.

MDIS reliability was also very high with the system functioning 99% of the operational time. Much of this reliability resulted from on-site support contractor personnel who worked diligently to ensure optimum performance of the equipment. In addition, MDIS' fault-tolerant, redundant architecture was also beneficial in ensuring reliability for the system operations. Availability of workstations is also an issue in adapting the organization process to this technology. Initially there were not sufficient workstations available for the clinicians. However, clinicians were able to accept this limitation mainly because they had a voice in the location of workstations. By the end of 1994, the availability of workstations is expected to be resolved.

e. Analyze And Manage Stakeholder Commitment

This principle is similar to the principle, "determine whether there is enough energy for change." The

objective of both principles is to analyze or determine the stakeholder's commitment. However, in order to analyze and manage stakeholder's commitment, the stakeholders need to be identified. Benjamin and Levinson seem to have overlooked this factor. For the MDIS implementation at Madigan, the stakeholders are: the U.S. Army's top medical leadership, the personnel at the MDIS Project Office, the contractors (Loral/Siemens), the radiology staff at Madigan, the clinicians at Madigan, the support personnel involved with the MDIS project, and finally the patients seen by the Radiology department. Some type of consensus building among all the stakeholders is paramount to gaining acceptance for the implementation process. Teams or task forces can create the momentum and commitment to obtain a consensus. Teams set the stage for open discussion, debate, and sharing of information. For the MDIS project a team of experts was established to develop the MDIS' technical specifications. Another MDIS team, particular to the implementation at Madigan, was Smith and Leckie who worked to facilitate the implementation process. For MDIS the success of teams and consensus building is evident by the acceptance rate of approximately 98% among the medical staff in one survey.

f. Provide Or Locate A System Champion

Champions of the system must be identified at the outset of the project to propagate the concepts of information

system design as well as its expected benefits among all potential users. Any stakeholder may fill this responsibility. There are usually two types of system champions dealing with a health care information system: the administrative champion and the physician champion. The administrative champion is responsible for providing an advocacy for funding and other key resources. For MDIS, this position was filled by the personnel working in the MDIS Project Office. The physician champion is responsible for (Bria, 1992, p.21):

1. Representing the needs and interests of the medical staff in the selection, design, testing, and implementation of the information system,

2. Communicating issues back to the staff at large,

3. Developing the policies and procedures necessary to facilitate use of the information system by the medical staff,

4. Recognizing opportunities to change current practices and policies to take better advantage of the information system for improving the quality and efficiency of care delivery,

5. Acting as advocates for the information technology.

At Madigan, the physician champions were Major Smith and Major Leckie. They were both well-recognized and respected leaders of the medical and radiology staff. Smith is a noted expert in PACS technology with a reputation as a "techie." He expended considerable time advocating the use of the system and training other members of the staff. Leckie is perceived as the insider looking out for the concerns and interests of

the medical staff. Leckie acts as the feedback channel for the Radiology department on the clinical acceptance of the system. Both Smith and Leckie have not completely abandoned their clinical radiology practice to serve on the implementation project. They have continued their visibility among other physicians.

The appointment of these system champions was the main key to the success of MDIS. Without champions, other staff may question whether the technology is really necessary and what commitment the leadership has towards the system. These champions were instrumental in advocating the merits of MDIS to the staff. Another noted champion of MDIS is Dr. Stigglebout. Stigglebout is an example for the other radiologists in the department to follow in his acceptance of MDIS. Not only could a physician of his age and experience adapt to the new technology, but he out-performed many of the young radiologists in his use of the system. He has aptly made the transition to the new technology, with the results being a shift in his radiology practice to more real time process review.

g. Prototype Organizational Response

Benjamin and Levinson provide little in the way of explanation about this and the next principle; both are feedback mechanism for the behavioral implications of implementing information technology. Communication and

feedback acquaint the user with the advantages and disadvantages of the information system. When all users of the system thoroughly understand the complexity of the system and its implementation, they will embrace change with a minimum of reluctance. As users of the information system grow more familiar with its operations, they can make recommendations to improve the technology and its implementation. In addition, communication also serves as a feedback mechanism to health care executives in monitoring the implementation process. The feedback publicizes its benefits, and thus encourages others to accept the system. In the implementation of MDIS at Madigan, several research studies were performed as a feedback mechanism to elicit organizational response. Surveys of the medical staff's satisfaction was the primary source of information for the acceptance of MDIS outside the Radiology department. The internal benefits of MDIS to the Radiology department at Madigan were demonstrated by the reduction in retake rate and greater image availability after the implementation of MDIS. These benefits helped sell the system to the radiology staff. Another feedback was the two-fold increase in productivity with fewer radiology technicians for the Gastro-Intestinal section of the department after going completely filmless. The accumulative results of these studies bears evidence to the benefits and success of the implementation of MDIS at Madigan.

h. Build Change Reviews Into Management Process

This last principle of Benjamin and Levinson's framework change model is similar to the preceding principle. Again, they advocate obtaining feedback as a means of supporting the change process. However, the military medical services usually are not willing to undertake this task because reviews usually take a considerable amount of time and resources to conduct. But this was not the case with the MDIS implementation at Madigan because of its high visibility from the outside radiology medical community. Smith, Leckie, and personnel in the MDIS Project Office have written extensively over the past two years reviewing and evaluating the implementation of MDIS at Madigan. As a result of findings in these reviews, the MDIS Project Office is currently undergoing reevaluation of institutionalizing MDIS throughout military medical services.

2. Hebert: Strategies for the Introduction of Information Technologies in a Hospital Setting

Marilynne Hebert also developed her strategies from a review of the literature on implementation of information technology and innovation diffusion theories. Her strategies differ from those of Benjamin and Levinson in that she advocates her strategy specifically for hospital settings. In addition, her change model takes into account the results of a survey she conducted on nurse behavioral response to a new bedside patient care information system. Hebert's change

model presents five objectives to be adopted in implementing a hospital information system (Hebert, 1994, pp.380-381).

a. *Clearly Identifying The Benefits And Advantages Of Using The New Technology Over The Current Practice*

This is a relatively clear concept. It is also similar to the points made by Benjamin and Levinson. While the benefits and advantages of PACS technology was discussed in Chapter II, many of the points brought up in Chapter II came from the military's early research and evaluation of PACS technology from such a project as DINS. The most important benefit of PACS technology is in the improvement of image management. With faster image accessibility and reliable image accountability, the military anticipates an increase in productivity of both clinicians and radiology staff and improvement in quality of patient care in military treatment facilities. Although insufficient to identify the benefits and advantages of this new technology, these factors need to be communicated to the stakeholders involved in the change process.

The system champions, in MDIS' case Smith and Leckie, are the change agents for the organization. It is their responsibility to communicate the benefits and advantages of MDIS and PACS technology throughout Madigan. Madigan experience with MDIS is also being publicized by Smith, Leckie, and the MDIS Project Office to the outside

radiology community as well. At the last Radiological Society of North America conference in Chicago, the MDIS Project Office had a booth which displayed the MDIS system. Radiologists from Madigan demonstrated the use of the MDIS workstations and interpreted radiological image from Madigan at the conference via a teleradiology link up. While the military is not endorsing the Loral/Siemens PAC system, it is the military's position to stimulate interest in PACS technology in the medical community and the medical industry. The MDIS Project Office has been perceived by many in the military medical services to have done an excellent job in marketing the MDIS system by pointing out its benefits. This marketing has one other major advantage. That is the military's expectation that this type of state-of-art technology will help with the recruiting of radiologists into the military as pointed out in Chapter II of this thesis.

b. Ensuring That The Prospective Users Perceive The New Technology As Being Compatible With The Current Values And Beliefs On Which The Organization Functions

Health care organizations tend to have a hierarchical and mechanistic structure. Physicians, at the top of the health care decision-making chain of command, typically have the greatest reluctance to adopt new technology. They prefer maintaining the status quo. Physicians find information system technology interesting only if they believe that it improves clinical effectiveness and

efficiency. Physicians see effectiveness and efficiency as meaning saving them time and effort in their clinical practice. Physicians want information systems to provide them with data as rapidly and as easily as possible, so that they can make their clinical decisions more conveniently. Health care information systems must now emphasize the potential benefits of improving patient care. In this regard, technology that promotes the physician's role and benefits patient care has a better chance of acceptance from clinicians.

MDIS is a patient care information system. As studies, like the Oschner Medical Center "length of patient stay," demonstrated in Chapter II of this thesis PACS technology improves the quality of patient care. In addition, as this case study showed, MDIS system was able to facilitate faster turnaround of radiological images, thus aiding patient care for the ICU clinicians. The Orthopedic surgeons were also receptive to the fact that MDIS reduced the number of retakes their patients required. The findings for the MDIS system clearly confirm that MDIS benefits patient care. This has significantly aided in MDIS acceptance by the medical staff.

c. Demonstrating That While The New Technology May Improve The Efficiency And Effectiveness Of Health Care Professionals, It Will Not Diminish Their Role As Care Providers

The medical staff and the health care executive management need to enter into a partnership to collaborate

from the starting point of any project to implement new technology so that all parties are involved in the process. Lieutenant Colonel Goeringer and other personnel at the MDIS Project Office have attempted to build this type of partnership with the radiology staff at Madigan during the MDIS implementation process. Radiologists and clinicians have been a part of the decision making process from the inception of the MDIS project. However, not everyone feels that personal input has been solicited, notably Colonel Babu. As head of the Radiology department, Babu should have been consulted prior to the decision to implement MDIS at Madigan. This is one point where the MDIS Project Office staff failed in its implementation process. Communication and collaboration in the decision making process appears to be the optimum way to ensure the role or position of health care professionals in the change effort.

d. Determining Who The Influential Referents In The Organization Are With Respect To A Particular Innovation And Including Them In The Change Process

Unlike Benjamin and Levinson, Hebert is also interested in the identity of the stakeholders in the change process. Otherwise this strategy is almost identical to the explanation given for Benjamin and Levinson's fifth principle, "analyze and manage stakeholders' commitment."

e. *Underscoring The Element Of Choice In The Range Of Applications Or Way They May Be Used, If Possible*

Hebert is not particularly clear as to the reasoning for this strategy. In her explanation, she equates the "element of choice" to providing alternatives. It can be assumed that she is advocating flexibility in the implementation of information systems. Thus, she views a phased approach as the best method for implementing health care information systems. As discussed previously, this was the process used for the MDIS implementation.

D. CONCLUSION

Both the Benjamin and Levinson and Hebert's change issue models have similarities in their approach to implementing information systems in an organization. Both see the implementation process as a change issue. Other areas of congruence between the two models are: need to communicate a vision, the requirement for advocating the beneficial incentives for change, the need for commitment by the stakeholders, user participation in change process, and the use of a phased implementation process. While Hebert does not mention the need for system champions, the major key success factor for the MDIS implementation was the system champion.

Benjamin and Levinson's model also put a significant emphasis on this role in the change process. Without dedicated individuals like Smith, Leckie and the personnel in

the MDIS Project Office, MDIS' success would not have been possible. The system champion is the agent of change for an organization. He is the one who can overcome the resistance to change. Change strategies such as the two models present are the tools for successfully implementing new technology; however, each model is not a cookbook procedure for implementing an information system. Strategy used by an organization should take into consideration the unique requirements for their culture and community. The MDIS implementation at Madigan followed many of the principles proposed in both change models, but the implementation did not correspond to either framework model completed. Additionally, the ease of use of the MDIS system and user participation have been other major advantages in making it easier for the user to adapt to this technology and requiring less time to devote to the learning curve, thus resulting in quicker acceptance.

Information systems must also be responsive to the demands of the user and reliable in providing access to the information that the user needs. Studies at Madigan have shown that MDIS appears to be achieving this goal. Thus, the factors that contributed to the success of implementing an information system in a health care organization are: vision, incentives, user participation, commitment, system champion, phased implementation, ease of use, responsiveness, and reliability.

VI. CONCLUSION AND RECOMMENDATIONS

A. CONCLUSION

With the ever expanding and more complicated delivery of health care, collection and distribution of information is critical. Consequently, timely management of medical imaging information is one of the greatest challenges facing medicine today. The capacity of conventional film-based systems to meet the needs of radiology departments has been shown to be inadequate when 69% of clinicians stated that image management was the greatest problem within radiology. Picture archiving and communication system (PACS) is an alternative to the conventional film-based system. The use of PACS offers many advantages in improved image management, image quality, productivity and patient care, and PACS will ultimately replace conventional film-based systems. The Medical Diagnostic Imaging Support (MDIS) project is the military's response to the implementation of PACS technology in selected U.S. military treatment facilities.

Madigan Army Medical Center was the first site chosen by the military to install the MDIS system. Madigan's experience with the implementation of MDIS has enjoyed wide acceptance among the medical staff. This acceptance has resulted in the MDIS implementation at Madigan being labeled a success. The

success of the MDIS implementation was due mainly to the selection and work of the system champions at Madigan. The use of champions facilitated managing the changing environment at Madigan with the progressive move to totally digital imaging information system for the Radiology department. The system champions provided the mechanism for better collaboration and communication. To overcome resistance to this change the system champions were a major factor. They brought enthusiasm, logical persuasion, and peer pressure to achieve acceptance. Clinical acceptability for the MDIS system has been a continuous process at each phase in the implementation of MDIS at Madigan, but the acceptability has remained at approximately 98% throughout the process. The greatest benefit of the MDIS system has been to the clinicians on the wards and in the clinics at Madigan. Although the MDIS system has required a substantial capital investment by the military, Madigan's implementation of MDIS has demonstrated that the economic benefits can be realized in saving clinicians' time and improving patient care with its improved image accessibility and availability. Thus, the MDIS system serves as a powerful tool for better health care delivery and for streamlining the management of diagnostic imagery in military treatment facilities. The MDIS system is the next step in the evolution of digital imaging technology to bring down the cost of health care and handle the increasing workload in military treatment facilities.

B. FUTURE RESEARCH

Implementation of PACS technology is just one part of the MDIS project. The MDIS project also encompasses teleradiology. Teleradiology is the ability to transmit, read, and interpret radiographic images over long distance telephone lines. Teleradiology holds great promise for providing support to remote locations such as battlefield and shipboard sites. With this possibility, the military medical community has been actively interested in teleradiology for a number of years. Recently, teleradiology has been used by the military services for the transmission of radiographic images from Somalia and Zagreb, Croatia, to Walter Reed Army Medical Center and Naval Hospital, Bethesda, Maryland. The impact of teleradiology in military medicine is one future area of this type of digital imaging technology. Additional research following the implementation of PACS technology at Madigan would also be beneficial in determining the implication of totally filmless radiology practice.

C. RECOMMENDATIONS

The sites chosen for the implementation of MDIS system did not include a Navy military treatment facility. To date the Army and Air Force have led the way in this technology. The Navy should consider taking a more active role in the MDIS project. A site like the new Naval Hospital Portsmouth, Virginia, would be ideal for the installation of the MDIS

system. A comparison could then be made between the experiences at Madigan and those at Portsmouth. The comparison between the two facilities would be beneficial in determining if the success at Madigan with MDIS' PACS technology could be institutionalized across the military medical services.

A second recommendation is that the use of physician system champions in the implementation of health care information systems be considered. A cadre of these physician champions would facilitate and stimulate the acceptance of the information systems in military treatment facilities. Their direct involvement in the implementation process would be critical to achieving success with other health care providers. With clinicians' involvement in information systems development and implementation, military medical services will see greater return and utilization of their investment in information technology.

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APPENDIX A

MDIS Performance Workstatement
"Technical Specifications"
This is only a technical part of a larger document from the U.S. Army.
October, 1990

The page numbers are different from the original document.

SECTION C

PERFORMANCE WORK STATEMENT

Part I - MDIS System Overview.

1.0. MDIS System Summary.

1.1. Introduction.

1.1.1. General.

The Medical Diagnostic Imaging Support (MDIS) system is a network of computer-based digital devices that will effectively manage medical diagnostic images. MDIS will significantly improve the quality, productivity and efficiency of medical radiologic practice as a major component of military health care. These specifications detail the performance requirements for an MDIS system at both large medical treatment facilities (MTF) and smaller MTFs requiring expert medical diagnostic imaging support. The system shall provide connectivity for image and patient data management in a multi-building MTF environment– referred to as an intra-MTF system– as well as transfer of images and associated patient data between MTFs. In some cases these MTFs can be separated by hundreds of miles; this configuration is referred to as an inter-MTF system with a centralized receiving 'hub' MTF supporting remote 'spoke' MTFs.

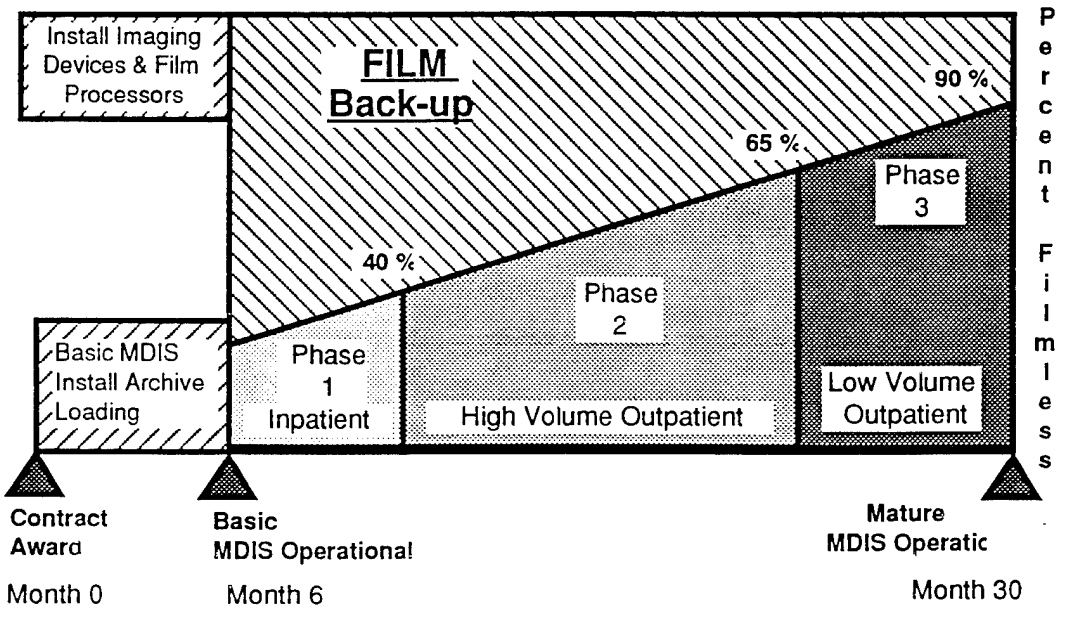
1.1.2. System Sites.

The first large MTFs to receive MDIS systems are Madigan Army Medical Center (MAMC), Fort Lewis, Tacoma, Washington, Wright-Patterson Air Force Base (WPAFB), Dayton, Ohio and Brooke Army Medical Center (BAMC), Fort Sam Houston, San Antonio, Texas. The smaller MTFs projected to receive this technology initially include inter-MTF system link from Luke AFB, Phoenix, Arizona to Davis-Monthan AFB, Arizona. Additionally, nine intra–MTF, twelve inter-MTF hubs, and up to 96 inter-MTF spokes follow on sites are also projected for this acquisition. The form and functionality of the follow-on MTF systems shall be the same as the initial implementations.

1.1.3. Time-Phased Installations.

Intra-MTF systems will be put into operation in a time-phased implementation plan over a period of 12 to 36 months after an initial delivery order is placed with the contractor. Each phase is a 'critical mass' that focuses on a specifically defined portion of radiologic imaging support. Typically, intra-MTF systems will be installed in a two or three phased implementation process over 24 to 36 months. This approach is designed to totally integrate MDIS systems technology into routine clinical use at an MTF. This acquisition includes complete "turn-key" installation at each individual location. The contractor shall provide MDIS systems solutions that stress a phased implementation with special focus on a sophisticated, total solution for the MTF over a period of time consistent with clinical utility and systems reliability. It should be noted that performance acceptance testing will be accomplished at the end of each phase prior to release into the next phase. Inter-MTF 'hub and spoke' teleradiology systems will be implemented in a more expedited fashion to meet immediate clinical needs; however the contractor shall also insure that basic capability is also in place at the hub MTF to guarantee future expansion– both between and within facilities. The following figure depicts a generic site MDIS implementation

Figure 1.1 Generic Site: 3 Phase MDIS Implementation



1.2. Basic Function.

1.2.1. General.

The function of the MDIS is to communicate and manage high quality digital radiologic image examinations for use in diagnosis and consultation by clinicians and other health care providers. The MDIS system is a network of computer based medical devices that (a) accepts digital diagnostic images, (b) communicates radiology information to and from the Radiology Information System (RIS), (c) archives and manages images and related data, (d) displays images and data at workstations for interpretation and consultation and, (e) communicates images and data to and from remote sites.

1.2.2. Basic Parameters.

The system shall preserve the full fidelity of the acquired image quality for image interpretation as images are generated by various radiologic imaging devices. In addition to the imaging devices listed in paragraph 1.3, the MDIS system requires computed radiography (CR) to acquire conventional radiographic images in a direct digital format as well as film digitizers to convert hard copy film images to digital format. The system shall include archiving of images and related patient information with minimum hard copy output. The number and sophistication of the soft copy image display workstations shall be dependent upon the radiology department's current and forecasted workload at each site. The transfer of images and patient data in the intra-MTF and inter-MTF configurations shall be done through networks and commercially available data grade links to meet throughput requirements in paragraph 8 below. The solution provided shall be modular and provide building blocks for all systems.

1.3. System Description.

1.3.1. General.

The MDIS system shall include all hardware, firmware and software to effectively manage and communicate diagnostic images and associated data throughout the network. This system is composed of image acquisition devices, data storage, data archive, image review stations, diagnostic reporting stations and image communications within and between MTFs. The MDIS System shall be integrated with the DOD standard. Composite Health Care System (CHCS) where appropriate to facilitate efficient network operations and data management. Where CHCS is not installed, the MDIS system shall provide for stand alone data entry, use of demographic data, order entry/order processing, and results reporting through an interim radiology information system (RIS).

1.3.2. Supported Imaging Devices.

The MDIS system shall support at least the following modalities: conventional film/screen radiography (CF/SR), computed tomography (CT), magnetic resonance imaging (MRI), ultrasound (US), nuclear medicine (NM), computed radiography (CR), video fluoroscopy (VF), digital fluoroscopy (DF), digital angiography (DA), digital subtraction angiography (DSA), and positron emission tomography (PET). The contractor shall provide a specific method for CR capability as well as the ability to introduce hard copy film based images into the system when required. The contractor shall provide complete installation, as specified for each individual location, including interfaces to local power, water, waste, communications, and data links.

1.3.3. MDIS Subsystems.

1.3.3.1. General. The MDIS System consists of 4 subsystems:

a. The Image Acquisition Subsystem
b. The Image Output and Display Subsystem
c. The Image Database and Storage Subsystem
d. The Communications Network Subsystem

1.3.3.2. The Image Acquisition Subsystem shall provide:

a. Computed Radiography: reusable phosphor plate radiographic systems to acquire conventional x-ray images in digital format.

b. Digital Film Digitizers: to convert conventional film images to digital format.

c. Standard interfaces to digital imaging devices: to integrate imaging devices such as computed tomography (CT), magnetic resonance imaging (MRI), and digital subtraction angiography (DSA). Digital interfaces shall be provided as described in paragraph 7.4.2.

d. Digitized video interfaces: to integrate video imaging devices such as ultrasound systems (see paragraph 7.4.1.3).

e. Paragraph 3 provides detailed subsystem performance parameters.

1.3.3.3. The Image Output and Display Subsystem shall provide:

a. Hard Copy Digital Film Output: this capability shall be on demand causing images to be produced from such devices as laser film printers.

b. Soft Copy Image Display (SCID): this capability shall be from two classes of display workstations– one for primary image interpretation and one for secondary clinical review.

c. Paragraph 4 provides detailed subsystem performance parameters.

1.3.3.4. The Image Database and Storage Subsystem shall provide:

a. Database Management: maintains the information integrity of the system to insure proper flow of images and data in and out of image storage to the clinical setting.

b. Interface to Radiology Information System (RIS): patient data interface between the RIS and the MDIS system as defined in paragraph 5.11,

c. Image Examination Storage: images and related patient data shall be stored in a combination of short-term storage and permanent long-term archiving devices to efficiently manage images and related data. This need will require the use of both magnetic as well as optical storage.

d. Paragraph 5 provides detailed subsystem performance parameters.

1.3.3.5. The Communications and Network Subsystem shall provide:

a. Image and Text Data: a combination of communications capability to physically transmit images and related data (e.g., diagnostic report and related overlays). In many situations, high speed networks using optical fiber or dedicated phone lines may be required. The communication media and protocol shall support transparent network operation.

b. Intra-MTF Network Capability: provides for the actual communications to move images within a medical treatment facility– either within or between buildings.

c. Inter-MTF Network Capability: provides for the actual communications for movement of image between medical treatment facilities–sometimes referred to as teleradiology.

d. Paragraph 6 provides detailed subsystem performance parameters.

1.3.4 Fail Safe Operation.

1.3.4.1. General. The MDIS system shall include safeguards to prevent loss of clinical functions and data. To insure a high level of system availability, the system shall continue operation and minimize inconvenience in the event of failure of components.

1.3.4.2. System Failures . These are defined as follows:

a. Soft failure of a component - requires a task to be repeated. No data is lost as a result of this failure.

b. Soft failure of the system - requires re-transmission of data or redirection of data to another working path, but does not involve any loss of data.

c. Hard failure of a component - the component malfunctions and requires corrective maintenance or replacement. Any component failure resulting in loss of data is a hard failure.

d. Hard failure of the system - an emergency situation which requires immediate corrective maintenance. The MDIS system cannot perform its function.

e. Soft failures of components and system shall be generally easily and quickly "rebootable" with a minimum of tasks and keystrokes.

f. Paragraph 10 addresses maintenance responses to these failures.

1.3.5. Two Methods for Systems Configurations.

As determined by the government at the time of execution of a delivery order under the basic contract, the contractor shall provide MDIS systems described in this solicitation according to one of two methods.

1.3.5.1. Method 1- Clinical Scenario Configuration. This method is according to the Clinic Scenarios attached as part A thorough E of the appendix to this section. Required procedures to propose configurations for these clinical scenarios are outlined in section L. Additionally, Schedules I and II of section B outline Contract Line Item Numbers (CLINs) for these scenarios for pricing. This method is envisioned to be the more common approach in acquiring MDIS systems.

1.3.5.2. Method 2- Custom Component Configuration. This method is according to component configurations as specified by the government in the award of a delivery order. This method is intended to meet clinical situations at MTFs that are not appropriate for MDIS configurations under method 1. Schedule III of section B lists individual major MDIS components for pricing. The contractor shall provide a system configured of components from schedule III that are specified by the government by delivery order after award of the basic contract. Installation and Systems Integration will be priced at the time of delivery order when this method is used.

1.3.5.3. Required Performance. Regardless of which method is chosen, the MDIS system shall meet performance as specified in this contract.

1.3.6. Component Additions or Deletions to System Configurations.

1.3.6.1. MDIS Component Additions. At the discretion of the government, systems configured by the contractor according to one of the two methods described above, may further be augmented by adding MDIS components that are identified in Schedule III of section B after award of the basic contract. The component price information provided by the contractor in section B will apply to this activity. Section L outlines procedures to submit information on MDIS system components. Added components shall meet the performance

described in this contract and not impede the performance of the entire system as specified in this contract. These components must be systems compatible with the systems specified in Schedules I and II.

1.3.6.2. MDIS Component Deletions. At it's own discretion, the government may delete a component from a configuration proposed under Method 1- Clinical Scenarios (e.g., a workstation) as part of the transaction of awarding a delivery order. Pricing to the basic configuration will be adjusted downward by the amount of the component, installation, integration and maintenance as priced by the contractor in Schedule III of section B. The government will not delete a component that prevents the entire system from functioning or that impedes total system performance.

1.3.7. Systems Integration and Turnkey Installation.

The MDIS system acquisition includes complete systems integration and "turn-key" installation as described in parts II, III, and IV below. The system shall include all equipment cabinetry, racks, stands, console surfaces for input devices, and other items necessary to provide a suitable working surface for the equipment. Ergonomically designed chairs shall be provided for all workstations.

1.3.8. Management Requirement.

The MDIS system is at the leading-edge of radiologic practice; consequently the contractor shall create and sustain an administrative management team within their organization that is capable of insuring the successful implementation and ongoing support of this system. A contractor with a sound management system shall possess the following characteristics:

a. An established market position in the medical digital imaging industry as a system integrator and/or component manufacturer with a history of success.

b. Research and development efforts which maintain the contractor's prominent position as a technology innovator in the industry. This strength includes demonstrated potential to produce new product, to keep the product line current, and provide ongoing support and product development.

c. A well established and logical hierarchical organizational structure with key project personnel and an experienced project manager in

medical filmless imaging. This organizational structure shall emphasize customer support and service and technology development.

d. Recruitment and retention of highly qualified, fully experienced, credentialed technical, clinical, research & development, managerial and project management personnel.

e. A demonstrated ability to establish and meet stringent performance schedules. This competence includes the ability to successfully manage multiple, conflicting schedules and priorities.

f. Experience in managing similar cutting-edge technology projects successfully. Current and former customer comments are positive concerning the contractor's project performance.

g. Well established relationships and and written, documented working agreements with vendors and sub-contractors with whom the contractor works.

1.3.9. Benchmark Requirement.

The simulation information provided by the successful offerer at benchmark test will be subsequently used as performance criteria in validation and acceptance testing at installed Government clinical sites.

2.0. MDIS System References.

2.1. General.

At the time of award of a delivery order, the most current version of the following applicable standards shall apply to MDIS system performance at a specific site. In the case of contractor discovered conflicting codes and/or standards, the contractor will identify the conflicts to the government who will resolve the conflict.

2.2. Applicable Documentation.

2.2.1. National Fire Protection Association (NFPA) Standards.

10 Series Portable Fire Extinguishers
13 Series Installation of Sprinkler Systems
70 Series National Electrical Code
72E Series Auto Fire Detectors
99 Series Health Care Facilities
101 Series Safety to Life from Fire in Buildings and Structures

2.2.2. Department of Defense Instructions (DODI) & Directives (DODD).

In their entirety without individual reference.

2.2.3. Army Regulations (AR).

AR 40-4 Army Medical Department Facilities/Activities
AR 40-60 Policies and Procedures for the Acquisition of Medical Material
AR 40-61 Medical Logistics Policies and Procedures
AR 40-62 Standard Policies, Definitions, and Data Presentations relating to Fixed Medical Treatment Facilities and Patient Accountability
AR 40-65 Review Procedures for High Cost Medical Equipment
AR 40-66 Medical Record and Quality Assurance Administration
AR 380-19 Information Security

SB 8-75 The Medical Care Support Equipment Program (MEDCASE)

2.2.4. Air Force Regulations (AFR).

AFR 88-15 Criteria and Standards for Air Force Construction

AFR 88-50 Criteria for Design and Construction of Air Force Health Facilities

AFR 88-40 Sign Standards

2.2.5. International Conference of Building Officials Publications.

Uniform Building Code, 1985

2.2.6. Illumination Engineering Society (IES) Publications.

CP-29-78 Lighting for Health Care Facilities

1981, IES Lighting Handbook, Application Volume

1984 IES Lighting Handbook, Reference Volume

2.2.7. Institute of Electrical and Electronics Engineers (IEEE).

602-1986 IEEE Recommended Practice for Electrical Systems in Health Care Facilities

IEEE 802.X Communications Standards

Medical Information Bus P1073

2.2.8. Federal Publications.

Uniform Federal Accessibility Standards (UFAS),1984

Federal Information Resources Management Regulations (FIRMR) in their entirety without individual reference to include:

Hardware Standards (Interchange Codes and Media)

Software Standards

Programming Language Requirements

Telecommunications Standards

Hardware Standards (Transmission)

Hardware Standards (Character Sets)

Software Standards (Documentation)

Federal General Standards (Data Standard Representations and Codes)

Federal Information Processing Standard (FIP PUBS)

Publications in their entirety without individual reference.

2.2.9. Military Standards.

Mil Std 1472D, Human Engineering Design Criteria for Military Equipment, Systems, and Facilities.

2.2.10. The Joint Commission on Accreditation of Health Care Organizations (JCAHO)

Accreditation Manual.

2.2.11. American Society for Testing and Materials (ASTM) Publications.

In their entirety without individual reference.

2.2.12. American College of Radiology (ACR)-National Electrical Manufacturers Association (NEMA) Standards.

ACR-NEMA Standard 300-19XX

ACR-NEMA Data Compression Standard PS-2

2.2.13. Occupational Safety and Health Act Regulations (OSHA).

In their entirety without individual reference.

2.2.14. Other Publications.

NAPHCC National Standard Plumbing Code

National Standard Plumbing Code (SPC)

Uniform Plumbing Code (UPC)

MICA National Commercial Industrial Standards

ASHRAE Handbook on HVAC Systems Applications

ASHRAE Handbook of Fundamental Requirements

SMACNA Duct Construction Standards

2.2.15. Certification of Listing and Approvals.

Certified copies of approvals, and/or submission of appropriate documentation for approval issued by Underwriters Laboratories (UL), FMRC, CSA, CYTEC or other nationally recognized testing laboratory (NRTL) showing compliance with applicable standards shall be provided to the Contracting Officer. Written evidence of submission to the FDA of hardware, firmware and software descriptions and good manufacturing practices shall be provided to the Contracting Officer.

Part II. - MDIS Subsystems Performance.

3.0 Image Acquisition Subsystem.

3.1. General.

Image acquisition shall be accomplished through the various traditional methods of radiologic practice as described in part 1 above. Direct digital acquisition is a requirement of the MDIS system. The contractor shall provide interface solutions for digital diagnostic imaging modalities and digital conversion solutions for conventional radiography according to the performance parameters described in this section.

3.1.1. Special Routing.

At each image acquisition site, there shall be a capability to route image examinations to designated hard copy printer or soft copy image display on the network. This function is termed special routing.

3.1.2. Emergency Routing.

At each image acquisition site, there shall also be an emergency examination override feature that interrupts processing of an existing on-going study at the first available interval between images and allows processing and routing of a 'STAT' image to a soft copy image display or hard copy printer device on an expedited basis.

3.2. Computed Radiography (CR).

3.2.1. General.

The contractor shall propose CR units which employ reusable photo-stimulable phosphor plate technology as a replacement for conventional film/screen processing techniques. Proposed CR devices shall be compatible with existing cassette X-ray imaging systems and their operational aspects shall be functionally equivalent to, or better than, the present film based system. Retrofit of cassette handling capability on radiographic devices to accommodate CR cassettes is not acceptable. In the event of MDIS network failure, a means shall be provided to produce hard copy output from CR.

3.2.2. Specific CR Performance.

Due to variations in clinical requirements and workload factors, three versions of CR performance (high, medium, and low) are required as described in the following table. Site specific solutions may include all three levels of performance.

Table 3.1 Requirements for Computed Radiography

Computed Radiograpl (CR) Attribut	Performance Requiremer		
	Higt	Mediun	Low
Throughput (plates / hour)	60	40	20
Multiple Plate Size Processing **	Yes	Yes	No
Input Stacking Capacity (Plates)	30	10	No
Spatial Resolution- 14" X 17" Plate Size	2.5 lp/mm	2.5 lp/mm	2.5 lp/mm
Spatial Resolution- 8" X 10" Plate Size	5.0 lp/mm	5.0 lp/mm	5.0 lp/mm
Dynamic Resolution- Minimum: 10 Bits/pixel	Yes	Yes	Yes
Image Processing	Yes	Yes	Yes
Max Footprint	NA	NA	12 sq ft Desktop

NOTES: * Numerical entries represent minimum acceptable performance levels, except where indicated otherwise.

** Varying plate sizes typical of those used in conventional radiography.

3.2.3. Additional Requirements.

In addition to the requirements contained in the above table the CR device shall have the following capabilities:

3.2.3.1. Device Diagnostics. The CR device shall perform self diagnosis and report error or fault conditions to the device operator and the MDIS network as described in paragraph 8.5.

3.2.3.2. Image Retention Time. Exposed image plates shall be capable of being held for up to four hours without a loss of observable image fidelity. This means that signal decay on the phosphor plate shall not degrade beyond 70% of its original acquisition value after 4 hours.

3.2.3.3. Image Processing. The device shall have automatic and user-selectable image processing capabilities which are selected in accordance with each anatomical region, projection and information requirement. At a minimum, the CR device shall perform variable degrees of edge enhancement. Pixel dimension information shall be communicated to the network for mensuration. The CR user shall have the ability to manually override the automatic setting and enter new image processing parameters. The user shall also have the capability to modify automatic image processing protocols.

3.2.3.4. Patient Radiation Dose. Patient radiation dose needed to acquire the diagnostic image shall be less than or equal to that normally required to produce the same image of identical quality using conventional film/screen techniques.

3.2.3.5. Preview Monitor. The device shall be equipped with a preview monitor which permits previewing of images prior to complete processing. The CR device shall allow the user to abort unacceptable previewed images prior to transmission to the MDIS network.

3.2.3.6. Examination Terminal. An examination terminal shall be provided for the technologists to view patient identification and examination information. The device shall provide the user with the ability to select or modify examination data. Any changes made to this information shall be communicated back to the radiology information system. Technologists shall be able to add or delete examinations from this terminal. The terminal shall allow the technologist to associate patient identification and examination information with the image plates being used for the examination.

3.2.3.7. Image Quality Control. The contractor shall provide a means to compute the mean amplitude and standard deviation of acquired image pixel values within user specified regions of interest. The technique provided shall also allow the technician to compute and plot line spread and modulation transfer functions- or some other test which correlates the MTF and is capable of measuring changes from the norm. The user shall be able to perform these functions while the device is in the clinical operating mode. In addition, the contractor shall provide a means to perform device sensitivity and linearity tests. These tests shall be capable of being conducted in the service or operational mode.

3.2.3.8 Network Interface. CR devices shall support the ACR/NEMA standard as described in paragraph 7.4.2.

3.2.3.9. Cassettes & Phosphor Plates. CR devices shall be provided with a suitable number of cassettes and phosphor plates to ensure normal operating throughput. These are termed as start-up supplies included with the device.

3.3. Interface from Digital Modalities.

3.3.1. General.

The contractor is responsible for providing a fully functioning interface to all digital modalities. This includes providing both the modality and MDIS network sides of the interface, where necessary. This interface shall accept and introduce digital images and associated text data into the MDIS network as produced from digital acquisition devices that are described in paragraph 1.

3.3.2. Systems Performance.

The performance of this interface shall not constrain the throughput from the imaging devices. Image transfer to the network shall require no more than a one key stroke equivalent. Systems throughput is discussed in detail in paragraph 7.4.

3.3.3. Direct Digital Acquisition (DDA).

3.3.3.1. CT and MR Devices. The contractor shall provide a digital interface as described in paragraph 7.4.2. This interface shall preserve the contrast and spatial resolution as well as image parameters (e.g., CT numbers, MR signal intensities) of the original acquisition device.

3.3.3.2. Other Digital Diagnostic Imaging Devices. Each MTF will have a unique nuclear medicine device configuration as well as unique configurations for other digital devices such as DSA. During the installation planning and site visit process, the contractor shall propose a technical approach to interface these devices to the MDIS system. These interfaces shall adhere to all performance and interfacing standards as described in other parts of this specification.

3.3.4. Digitized Video Acquisition.

The contractor shall provide an interface to introduce analog images for ultrasound. Input of patient text data shall use the text data output of the imaging device or, if this is not available, a text terminal, bar code reader, or equivalent. If a text terminal is used, manual input shall not exceed typing the patient name and/or patient number. Response time (ready to accept the next image) to the technologist acquiring the video digitized images shall not exceed two seconds under any network load condition. Further discussion of digitized video is described in paragraph 7.4.1.3.

3.4. Film Digitizer.

3.4.1. General.

The contractor shall provide film digitizers to convert radiographic films to digital images. Two levels of performance are required.

3.4.2. Film Digitizer Requirements.

The following table depicts film digitizer requirements.

Table 3.2 Film Digitizer Requirements

Requirement	High Performanc	Low Performanc
Sheet Feed	Yes	No
Spot Size	Variable (auto adjust)	fixed
Maximum Spot Size	Not larger than 210 microns	Not larger than 210 microns
Dynamic Range *	10 bits minimum	10 bits minimum
Throughput	60 Sheets/Hour at maximum resolution	30 Sheets / Hour at maximum resolution

* Dynamic range is the number of bits of true data in each pixel.

3.4.3. Additional Requirements.

3.4.3.1. Film Sizes. The film digitizers shall accept conventional x-ray films from 8"x 10" up to 14"x 17". The device shall be able to determine the film size automatically. The high performance digitizer shall auto-adjust the laser spot size accordingly.

3.4.3.2. Automatic Sheet Feeder. The high performance digitizer shall have an automatic sheet feeder. This sheet feeder shall be able to hold and automatically feed a minimum of 10 x-ray films of intermixed size.

3.4.3.3. Presentation to the Network. The digitizer shall send preprocessed digitized images to the MDIS network at a minimum rate of one image per minute. The digitizer shall have processing capability to perform contrast rescaling to guarantee consistent opacity from one film to another.

3.4.3.4. Network Interface. The film digitizer shall support the ACR/NEMA standard as described in paragraph 7.4.2.

3.4.3.5. Preview Monitor. If the digitizer is not used in conjunction with a local workstation, the contractor shall provide an image preview monitor at the digitizer. The digitizer shall allow the user to abort unacceptable previewed images.

3.4.3.6. Device Diagnostics. The device shall perform self diagnosis and report error or fault conditions to the device operator and the MDIS network.

3.4.3.7. Automatic Data Entry. The high performance digitizer shall provide a means to automatically enter uniquely identified patient and exam data into the MDIS network.

3.4.3.8. Film Density & Signal to Noise. The nominal film digitizer operating range shall be over a density range of OD = 0 to OD= 3.5. However, since many medical films have a Dmax>3.5, a selectable range is required as a accessory on the high performance digitizer. S/N will change as OD changes. Mean noise at the greatest OD that the digitizer accepts shall not exceed the least significant 4 bits for a 12 bit range or the least significant 2 bits for a 10 bit range. Resolution, as determined from the MTF, shall be sufficient to resolve 2.5 lp/mm.

3.5. Fluoroscopic Systems.

3.5.1. Photospots.

The contractor shall propose a method for the input of photospot images (those obtained from the image intensifier) from radiographic/fluoroscopic systems supported by MDIS. If a digital output is available from such systems, the interface shall follow parameters described in paragraph 7.4. If no digital interface is present, digitization of the video signal from the image intensifier camera is acceptable provided the requirements of paragraph 7.4.1.3 are met. It is not expected that the real-time fluoroscopy will be digitized, only the image which would normally be recorded as a photospot film. This technique shall also provide for input of appropriate patient data as described in paragraph 3.3.4.

3.5.2. Spot Films.

Conventional spot film images shall be handled by using CR plates in the spot film device.

3.6. Images Produced by Portable Imaging Systems.

In some MTFs, ultrasound and c-arm fluoroscopy units are moved to various locations in the facility. The contractor shall propose methods to input images from these systems into the MDIS when they are used in a "portable" application. Digitizing films is not an acceptable method for accomplishing this function. Portable radiographic units shall be supported by CR.

4.0 Image Output and Display Subsystem.

4.1 General.

Image display and output consists of hard and soft copy versions of medical images. Hard copy outputs include films produced from an analogue or digital laser imager and radiologic teaching slides from a 35 mm slide device. Soft copy outputs are defined as images produced on imaging workstation monitors using digital data. The contractor shall propose methods of accomplishing both techniques for display of medical images according to specific performance parameters described in this paragraph.

4.2. Laser Film Imager.

The MDIS system shall include analogue and/or laser multiformat imagers with the following performance features. The number of imagers at each site will be based on the volume of images produced. The laser printer shall be fully integrated with a film processor- requiring a minimum footprint. It shall follow ACR NEMA standards as described in other parts of this document.

4.2.1. Film size.

The imager shall have the capability to record images in multiple image sizes, including 14 x 17 inch, 11 x 14 inch, 10 x 12 inch, 12 x 12 inch and 8 x 10 inch. This performance feature may be met through the use of appropriately sized film magazines. The imager shall provide at least seven image formats–1:1, 2:1, 4:1, 6:1, 9:1, 12:1, and 15:1. The imager shall be capable of carrying 12 bit pixels from the input to the output digital to analog converter in the device.* The printed image matrix size shall be equal to or greater than that of images that are acquired for the network.*

4.2.2. Safety features.

The imager shall be equipped with interlocks or warning lights that prevent double exposure, exposures with film in the wrong position, incompatible film sizes, and improper film insertion and removal.

4.2.3. Laser Imager Operation.

Image selection and film format shall be controlled from specifically designated diagnostic and clinical workstations as identified by the systems manager. The imager shall print the image as it was acquired or stored on the archive, including the requirement for image overlays and patient data when specified at the time of print request. Requests for printing shall run in background mode and will not compromise the workstation operation while the image is being printed. The workstation shall indicate the image is being printed and the identification of the requestor shall be printed on the border of the film.

4.2.4. Automatic Film Handling and Transfer.

The imager shall include an automatic bulk film load system with daylight capability. Two loading magazines for each film size specified above, capable of holding 100 or more films each, shall be provided. Two receiving magazines for each film size specified above, capable of receiving at least 100 films, each shall also be provided. All magazines do not have to be on-line simultaneously, and manual intervention to configure a printer for a selected film size is acceptable. The laser imager shall be fully integrated with the film processor. The processor shall have a cycle time of not more than 90 seconds, and be capable of processing at least 120 sheets of 14 x 17 inch film per hour. Only ambient water shall be necessary for normal processor operation; water temperatures from 40 to 90 degrees F (4-32 degrees C) shall be acceptable.

4.2.5. Quality Control/Calibration.

The imager shall allow the user to manually adjust image contrast and density. A digital test pattern (SMPTE or equal) shall be provided in the device for quality assurance and device verification. The imager shall also have calibration capabilities using built in test patterns.

4.2.6. Multiple film originals.

The imager shall produce multiple copies of the same image with one request. This feature shall be selectable from the requester's workstation. If more than ten copies of any single film are requested, the supporting MDIS system software shall ask the requestor for verification.

4.2.7. Error and Status Indication.

The laser imager shall include a self diagnostic capability which shall indicate the following error and system status conditions: film low, film empty, memory full, film feed error, printing, and alarm.

4.2.8. Retrofit or Replacement for Existing Laser Printers.

When required on a site-specific basis, the contractor shall accomplish a retrofit/replacement MDIS network interface for any on-site laser printers that currently may be directly interfaced to on-site imaging devices such as CT or MR systems. Such a retrofit/replacement option will be at the discretion of the government.

4.3. 35 mm Slide Production.

The MDIS system shall produce a 35 mm slide format from designated workstations on the network as determined by the specific site. Any selected region of interest on the image including the entire image shall be made into a slide format upon request from the workstation– including magnification (zoom) views. The slides shall include any image overlays or patient data displayed on the image at the time of request. This slide formatting shall be accomplished automatically, with no operator intervention.*

4.4. Soft Copy Image Displays (SCIDs).

4.4.1. General.

The MDIS system requires two classes of workstations for soft copy image display (SCID), the diagnostic workstation and the clinical workstation. The following table describes the required performance for these two workstations. Workstations shall be provided with ergonomically designed chairs for the operator. The narrative following the table describes the individually required performance attributes in detail.

4.4.2. Display Monitors.

4.4.2.1. General. Each diagnostic workstation shall be configured with from one to eight monitors. Three classes of monitors are required– class A, class B, and class C. A clinical workstation configured with one class C monitor shall be upgradeable to two class C monitors. Additionally a diagnostic workstation may be configured with A. B or a combination of both A

and B monitors in a portrait mode only. Color monitors are not acceptable to view grey scale images. The color modalities (e.g. color-flow ultrasound) shall use their own intrinsic monitors.

4.4.2.2. Class A, Class B, and Class C Monitors.* The class A monitor shall have no less than a 1536 by 2048 pixel matrix size. The class B monitor shall have no less than a 1024 by 1280 pixel matrix size when used in a diagnostic workstation. The clinical review workstation class C monitor shall have no less than 880 by 1150 pixel matrix size and can be used in a portrait or landscape mode depending on the clinical workstation configuration. The actual viewable raster diagonal of either monitor shall be no less than 17 inches and no greater than 23 inches diagonally. All pixel measurements in this document (e.g., 1024 x 1280) shall indicate horizontal and vertical dimensions respectively unless otherwise indicated.*

Soft Copy Image Display (SCID) Tables

Table 4.1
Workstation Hardware

Attribute:	Diagnostic Workstation	Clinical Workstation
Number of Displays	1-8 monitors	1-2 monitors
Monitor Type****	Class A, B, or Both	Class C
Spatial Resolution**** (pixel matrix)	A >/=1536 x 2048 B≥1024 x 1280- Portrait	>/= 880 x 1150 or >/=1150 X 880
Viewable Raster Diagonal	18"to 23 "	18" to 23"
Data set- Rad Images	Full Data Set	Downsampled Data Set
Brightness (luminescence)****	A,>40 /B,>60 FtLamberts	C, > 60 ft Lamberts
Viewable Greyscale Display	8 bits	8 bits
Refresh Rate****	Flicker Free	Flicker Free
Monitor Calibration	Yes	Yes
*Brightness Uniformity	<5%	<5%
*Linear Distortion	<3%	<3%
*Geometric Distortion	< 3%	< 3%
*Spot Size Variation	<10%	<10%
Frame Buffer	12 bits	8 bits or greater
Auxiliary Output for Slave Monitors	Yes	Yes

Note: All * items are measured concurrently

Table 4.2
Workstation Functions

Workstation Functions	Diagnostic Workstation	Clinical Workstation
Pictorial Image Directory	Yes	Yes
Worklist / Patientlist	Yes- Worklist	Yes- Patientlist
Display on Single Monitor	Multi-images	Multi-images
Image Rearrangement within & between Monitors	Yes	Yes
Paging within Exam	Yes	Yes
Edge Enhancement	Process/Display	Display
Window/Level Adjustment	Yes	Yes
Inverse Video	Yes	Yes
Image Roam	Yes	Yes

Table 4.3
Default Display Protocol

Default Display Protocol	Diagnostic Workstation	Clinical Workstation
Image Orientation	Yes	Yes
Modality Specific	Yes	No
Body Part Specific	Yes	No
Site Specific	Yes	No

Table 4.4
Image Enhancements Defaults

Image Enhancements Default	Diagnostic Workstation	Clinical Workstation
Window & Level	Yes	No
Inverse Video	Yes	No
Edge Enhancements	Yes	No
Site Specific	Yes	No

Table 4.5
Image Manipulation

Image Manipulation Tools	Diagnostic Workstation	Clinical Workstation
Window / Level All & Individual Images	Yes	Yes
Cursor Across All Screens	Yes	Yes
Zoom, Replicated	Yes	Yes
Zoom, Interpolated****	Yes	No
Digital Magnifying Glass	Yes	Yes
Sequential 90 Degree Rotation	Yes	Yes
Horizontal Flip	Yes	Yes
Vertical Flip	Yes	Yes

Table 4.6
Image Supplements

Image Supplements****	Diagnostic Workstation	Clinical Workstation
Auto Screen Blanking	Yes	Yes
Mensuration	Yes	Display Only
Text Annotation	Yes	Display Only
Graphic Annotation	Yes	Display Only
Image Identification	Yes	Yes
Hounsfield Units & Statistics	Yes	No
Delete	Yes	Yes
Hard Copy Generation	Yes	Yes
Undo (1 keystroke equivalent)	Yes	Yes
Save	Yes	No
Printer/Spooling Capability	Yes	No
System is working	Yes	Yes
Background autorouting	Yes	Yes
Examination Consultation	Yes	Yes

4.4.2.3 Data Sets Available to the Monitors. The full data set of acquired images (e.g., 2K by 2.5K 10 bit CR images) shall be available for viewing when the diagnostic workstation is configured with class A or B monitors. The clinical workstations for remote

viewing shall be configured with class C monitors. These clinical workstations shall utilize 1K by 1.2K by 8 bit downsampled data sets for laser film digitized and computed radiographic images; other modalities will utilize appropriate matrix size but all will be downsampled to not less than 8 bits of dynamic range for remote viewing. The utilization of mensuration, text annotation, and graphics annotation as defined below shall not reduce the number of gray levels of the image when displayed simultaneously with these functions. The downsampled data image sets will accurately display any overlays associated with that image.

4.4.2.4. Brightness (Luminance). Greater than or equal to 40 foot-Lamberts for a class A monitor and greater than or equal to 60 foot-Lamberts for a class B and C monitor shall be provided.

4.4.2.5. Gray Scale Display. No fewer than 256 shades of gray (8 bits deep) displayed on each monitor shall be provided.

4.4.2.6. Refresh Rate. This shall be high enough so the monitor is flicker free at standard viewing intensities for 95% of observers. The monitor is to be flicker free for 95% of observers with a SMPTE pattern displayed when adjusted to 90% of maximum intensity and observed under maximum ambient illumination of not greater than 10% of the monitor intensity.

4.4.2.7. Calibration. Brightness and contrast adjustment range of the monitors shall support matching of the monitor grayscale displays to < 5%. Three-month drift of monitor brightness and contrast shall be < 5%.

4.4.2.8. Uniformity and Distortion. The monitor shall have less than 15% brightness uniformity degradation from the center to the periphery. The monitor shall also have less than 3% linearity and 3% geometric distortion from center to periphery.

4.4.2.9. Monitor Electron Beam Spot Size.* The spot size shall vary less than 20% from center to diagonal corner of each monitor. This is measured from a viewable area 1/2" inside the perimeter of the monitor.*

4.4.2.10. Frame Buffer. Shall be no less than 12 bits deep for diagnostic workstations and 8 bits deep for clinical workstations.

4.4.2.11. Slave Monitors. The workstation shall have a slave monitor auxiliary output connection to reproduce the same single image across multiple monitors. A video signal conversion option for standard television shall also be provided for manipulation of images on

multiple television monitors from a clinical workstation. A Class B slave monitor is required for support from a diagnostic workstation; standard television is acceptable for support from a clinical workstation. The maximum distance for slave monitor location from the supporting workstation shall be 60 feet.

4.4.3. Workstation Functions.

4.4.3.1. General. The contractor shall provide multiple image manipulation and enhancement functions for the workstation. The following are required performance parameters.

4.4.3.2. Pictorial Image Directory. See paragraph 5.5

4.4.3.3. Worklist/Patient list. The diagnostic workstation shall automatically generate a worklist of unread (those images not already dictated) exams to enable each radiologist to review the amount of work ready for review. The worklist can be created for a specific radiologist or type of workstation and be dynamically updated for each workstation (e.g., CT diagnostic workstation). A patient list shall be displayed on each clinical workstation to provide a roster of images in local storage.

4.4.3.4. Image Rearrangement and Display. The workstation shall allow display of multiple images on a single monitor with a rearrangement capability. Rearrangement of images between monitors also shall be possible.

4.4.3.5. Image Paging. Quick sequential paging (stacking) through user-selected images of an exam displayable on a single monitor shall be provided.

4.4.3.6. Default Display Protocol. This required function displays the images of a patient study in a user-selectable protocol, activated each time the individual user logs on the workstation. If no individual default exists for user, the department default and protocol is utilized. The default display shall be modality and body part specific. It shall also be a site-specific selectable– i.e., each MDIS site shall be capable of setting its own parameters.

(For example– a patient has new posterior-anterior (PA) and lateral chest studies to be interpreted and has a previous comparison study. The radiologist viewing the study prefers to view the PA images on the central two monitors and the lateral images on the outer two monitors of a four monitor workstation. The radiologist also prefers to view the lateral images with the anterior border of the chest closest to the left monitor edge, the new PA image on the right central monitor, and the previous PA image on the left central monitor.)

Additionally, the preferred operation is to automatically present the image in an upright as well as correct right/left orientation. The minimum requirement shall be to allow the user to orient the image in a user selectable presentation.

4.4.3.7. Image Enhancements Defaults. The workstation shall include multiple user-selectable image enhancement defaults for grayscale windowing and leveling, variable degrees of edge enhancement, and inverse video, activated each time the individual user logs on the workstation.

4.4.3.8. Edge Enhancement. The workstation shall process and display the image with a user selectable degree of edge enhancement (e.g., unsharp masking).

4.4.3.9. Window and Level. The workstation shall provide dynamic window and level through the entire image grayscale data set for a diagnostic workstation. This function shall be provided for images on all monitors, a single monitor, or a specified region of interest on a single monitor.The minimum requirement for a clinical workstation for CT and MR images is to present discrete window and level images of the same image "slice" as determined by MTF protocol. (e.g., the "lung" and "mediastinal" images of each digital "slice" in a CT of the chest would be sent to a clinical workstation for review).

4.4.3.10. Inverse Video. Display of the inverse video of any selected region of interest shall be supported.

4.4.3.11. Cursor. The workstation control cursor shall move easily within and between monitors in a smooth continuous manner. The cursor shall always be visible during its movement. Cursor movement shall be controlled with a pointing device (mouse or trackball). The use of keyboard keys for the image cursor movement is not acceptable.

4.4.3.12. Screen Blanking. The workstation shall include automatic screen blanking with a user-selectable time default.

4.4.3.13. Zoom. Both categories of the workstation shall be capable of enlarging the workstation two and four times and display it by simple replication of pixel values. The diagnostic workstation shall also be capable of enlarging the image two and four times and display it by interpolation.

4.4.3.14. Image Roam. The workstation shall provide smooth continuous movement of a 2K by 2.5K by 10 or 12 bit image data set in the workstation memory through a 1K by 1.2 K window of a class B monitor utilized in a diagnostic workstation. If a class A monitor is used,

then image roam shall be a feature to view the entire image where appropriate. The zoomed images shall be viewable by the image roam function.

4.4.3.15. Digital Magnifying Glass. The workstation shall be able to display the full data set of a computed radiography image within a region of interest (ROI) on a class B monitor utilized in a diagnostic workstation or a variable degree of zoom within a region of interest for any image on either a class A or B monitor in a smooth, continuous manner.

4.4.3.16. Rotation and Flip. The workstation shall allow sequential 90 degree clockwise and counter-clockwise rotation of the image as well as 180 degree flip in the horizontal and vertical axes.(e.g., right to left or top to bottom). The new orientation shall be saved for future retrieval

4.4.3.17. Mensuration.* The workstation shall compute point-to-point measurement with automatically calibrated, user-selectable scales (e.g., cm or inches). It shall also perform angular measurement, area and perimeter measurement based on ellipses and pointing device control tracing. The workstation shall also determine the proper size of a orthopedic prosthesis utilized at given MTF's for surgical planning of various joints (e.g. hip joint) by an interactive process . These will be determined from computed radiography images of the joint considered for surgery. *It shall compute and display these functions for multiple measurements simultaneously (10 or less) on the same image and save them as an overlay which can be toggled on and off.*

4.4.3.18. Text and Graphics Annotations. The workstation shall utilize and display user-selectable locations and orientations for graphic symbols (e.g., arrowheads and circles) and text annotation with simultaneous displays on the same image. The annotation shall be saved as an overlay which can be toggled on and off.

4.4.3.19. Image Identification. When the images are displayed, the images shall be identified with the following patient data as a minimum; patient name, social security account number (SSAN) with the family member prefix (FMP), and the exam date and time.

4.4.3.20. Hounsfield Units and Statistics. The workstation shall compute and display mean and sample standard deviation of Hounsfield unit values in selected region of interest (ROI), including ellipses and irregular outlines as described. This feature shall allow multiple measurements on the same CT image. The annotated CT image shall be saved and the overlay toggled on and off.

4.4.3.21. Delete. The workstation shall be capable of user-selected auto-delete from local storage, and allow marking of selected images for non- deletion.

4.4.3.22. Hard Copy Generation. The workstation shall include a one keystroke equivalent (OKSE) method for image hard copy generation of an image selected from the workstation console. This function shall be controllable by the site systems administrator.

4.4.3.23. Command Reversal (Undo). The workstation shall be capable of reversing the last one key command and in the event that the command is not reversible the operating system shall indicate such a condition by a warning signal issued prior to executing the requested command.

4.4.3.24. Save.* The system shall allow authorized users to save selected teaching and research images using reversible image compression.*

4.4.3.25. Printouts. Worklists shall be printed on demand near each diagnostic workstation location with a one keystroke equivalent command.

4.4.3.26. System is Working (SIW). User operations that require time delays, for example some image processing operations, shall be indicated on the screen (e.g., a ticking icon) to let the user know that the operation is underway and the system is operating.

4.4.3.27. Autorouting in Background. Workstation performance shall not be impeded by autorouting operations. This activity shall be transparent to the user and not compromise the throughput of the MDIS system.

4.4.3.28.* Examination Consultation. It shall be possible to display the same examination on more than one MDIS workstation simultaneously. One feature of autorouting may be to support this requirement. The intention is to support consultation between health care practitioners. In this regard, real time simultaneous interactive cursor control shall be supported between workstations equivalent types.*

4.5 Specialty Workstation.

The contractor shall provide a specialty workstation that can display CINE images and 3 dimensional images. The workstations shall have the following performance characteristics:

Cine. When using a CINE function, the workstation shall display 2 through 26 frames of images at a rate selectable from 1 to 16 frames/sec. The images will be 256 x 256 x 8 bits or 512 x 512 x 8 bits.

Multiplanar reformatting. The workstation shall display user selectable reformatting at any plane for CT and MR data sets.

3D. The workstation shall be able to assemble 30 CT images and reform them into a three dimensional data set within 5 minutes and display 3D data set interactivity.

The contractor is free to propose additional capability for the government's consideration. This workstation is identified as a priced option in section B.

4.6. Image Downloading into CHCS Providers Workstations.

4.6.1. Basic Approach for the Provider Workstation.

CHCS provides for an enhanced data terminal– the provider workstation or PWS– to selected users to improve the efficiency and acceptability of the CHCS user interface. The PWS runs on VAXStation 3100 hardware. No MUMPS software (CHCS application software) runs directly on the PWS but CHCS applications will be accessible through the PWS. The PWS runs MOTIF, a graphical user interface which provides windowing capabilities. The contractor shall configure the PWS to support MDIS image downloading and display. This capability shall be on demand from the PWS through ethernet, using X windows under the MOTIF standard. The PWS workstation is regarded as a tertiary level workstation with limited MDIS image management functionality– less than the clinical workstation. The image displayed is considered a 'reference image'. Image manipulation and quality standards specified above for the diagnostic or clinical workstations do not apply. The contractor is free to propose alternative performance capability for the government's consideration. The approach is listed as a priced option in section B. Section J provides additional background information on the PWS.

4.6.2. Minimum Requirements for Image Downloading .

As a minimum requirement, the contractor shall propose a system that is capable of image downloading through a gateway into an ethernet environment beyond the clinical workstation environment using the TCPIP protocol.

5.0 Image Database and Storage Subsystem.

5.1. General.

The contractor shall provide an Image Database and Storage Subsystem with the following performance features indicated in the paragraph below.

5.2. The Image Database.

The MDIS database shall serve as patient image exam manager. As such, it shall (a.) accept and store image exams through the inter-MTF or intra-MTF network that are acquired by image acquisition devices, (b.) communicate stored and newly acquired images across the network on demand or by a logical autorouting algorithm to individual workstations or hard copy devices either for reference with the accompanying previous radiologic interpretation or for initial interpretation, (c.) automatically restore exams according to a predetermined procedure and (d.) function through an interface with the interim radiology information system (RIS) or with the DOD Composite Health Care System (CHCS), or the Composite Health Care System-Radiology as applicable.

5.3 Image Storage.

Depending on system architecture, image storage may be distributed throughout several hardware components on the network. Implementation of image storage hardware shall flow from and support the logical design of the database. Hardware may include digital storage devices such as magnetic tape and Winchester hard drives– including parallel transfer disks, erasable and non-erasable optical disks and related juke boxes as well as other emerging technologies such as optical tape devices as they apply to medical imaging.

5.4. The Logical Design – Short-term Storage and Long-term Archive.

The image database shall make use of design strategies to optimize cost and performance tradeoffs between image archiving efficiency and image delivery times. Specifically, logical designs are required that feature (a.) short-term storage for high demand imaging exams for fast retrieval and (b.) long-term archiving for low demand imaging exams for slower retrieval. The discussion in paragraphs 7 and 8 regarding fast and slow image throughput times applies.

5.4.1. Definition: Short-term Storage (STS).

Images and related information that shall be in the short-term storage are (a.) exams that are newly acquired in the past 48 hours, (b.) exams awaiting primary interpretation (c.) exams acquired in a period equal to the the facility's average length-of-stay for inpatients, (d.) selected historical exams for autorouting to a clinical area according to a daily clinic appointment schedule, and (e.) selected supporting historical exams of patients who have had new image exams. Short-term storage may be centralized or distributed throughout the system. Design strategies such as activity-based caching may be acceptable approaches, provided that STS throughput performance can be maintained or exceeded, for the image categories specified here.

5.4.2. Definition: Long-term Archive (LTA).

This archive shall contain all images and related information necessary to support (c.), (d.), and (e.) in the sub-paragraph directly above. The long-term archive shall be capable of storing the current year plus 4 additional years of imaging exams for a total of 5 years of imaging exams. Additionally, there are certain instances where exams must be retained for longer periods- e.g., pediatric images must be retained until a patient's 21st birthday or digitized post-interpreted mammography exams must be retained for the life of the patient. The particular archiving periods shall be site-specific and identified in further detail prior to issuance of delivery orders.

5.4.2.1. On-Line and Off-Line Long-term Archive. Images up to two years old may be in the on-line long-term archive. Images older than two years may be in the off-line archive.

5.4.2.2. Operations between Short-term Storage and On Line Long-term Archiving. These operations shall be a database automatic operation– i.e., no human intervention shall be required to archive or restore an image and related information between the short-term and long-term archive.

5.5. Use of the Folder Concept.

Patient exams shall be managed under the metaphor of folders which contain both interpreted images and related diagnostic reports. Folder organization shall be capable of hierarchical organization by patient, by exam body part, by modality (e.g., CT), by departmental section (e.g bone).

5.5.1. Folder Contents.

The patient master electronic file folder shall contain all the exams and reports. It shall be "opened" at the diagnostic workstation to display multiple minified reduced resolution images and diagnostic reports. This design approach is termed "pictorial image directory" or "PID." Each exam within the file folder shall be capable of holding up to 200 images (e.g., a large MR exam).

5.5.2. Review of Images from Several Exam Folders.

At the display, it shall be possible to select and simultaneously review various images and related reports at full resolution from different selected exam folders.

5.5.3. Creation of Teaching Folders.

Additionally, the creation of teaching folders shall be possible. These folders shall hold versions of clinically useful exams and reports for medical education and research. Folder organization shall be hierarchical– with sorts at the radiology (or other) department level, at the department section, and at individual physician level. Retrieval of exams from teaching folders shall be by individual or multiple database elements (e.g., requesting all exams within a particular diagnosis or age range).

5.6. Use of Compression.

5.6.1. General Approach.

The data compression strategy shall be site-specific and offer the option of both bit-preserving and non bit-preserving compression techniques for exam management. Reasonable compression ratio options range from 2:1 to 10:1.

5.6.2. Digital Microfilm Option.

A site-specific scenario where image exams can be displayed at full acquisition device resolution prior to primary interpretation followed by post interpretation long-term archiving at compression ratios of up to 10:1 shall be provided. Moreover, this post interpretation long-term archiving compression operation shall be site-specific and capable of being varied by (a.) type of exam and (b.) acquisition modality. This operation is termed 'digital microfilm'.

5.7. Use of Image Supplements.

The database shall retain image supplements, i.e.,annotations, measurements, default viewing attributes as bit plane overlays that help in image interpretation. These supplements shall accompany the basic image during display at any workstation or on printed laser film images when required.

5.8. Use of Exam Queries.

User interrogations for exam retrievals from the database shall permit (a.) simple to use query techniques for the non-sophisticated user and (b.) retrievals based on multiple sort of data fields as selection criteria (e.g., exam type, date, and patient birthday). This shall include an interactive capability.

5.9. Exam Security and Unauthorized Access.

Electronic safeguards of the exam database shall provide the equivalent level of security required for film-based image management systems. These safeguards shall prevent unauthorized access to images and exams. The contractor shall provide features and assurances that meet at least the "C2 level of trust" as defined in DOD 5200.28-STD; however, data encryption is not required.

5.10. Loss of Image Information.

Precautions against catastrophic loss of imaging exams shall be embedded in the database design. This may include techniques such as redundant image storage of high demand images on the short-term archive prior to long-term archiving.

5.11. Radiology Information System (RIS).

5.11.1. Three Implementation Approaches.

The MDIS system shall provide for stand alone entry and use of demographic data, exam data and result entry/reporting data where the CHCS (or CHCS-Rad) is not installed or, if installed, when it is off-line. The contractor shall support three types of radiology information system (RIS) implementations depending on the specific situation at the MTF. These three are–

One: Interim RIS. This shall be a contractor-provided RIS that shall fully support MDIS until such time as one of the DoD standard systems is implemented and when the DoD system is off-line.

Two: CHCS-Rad. This is also known within the DoD as IOC-R Radiology, Initial Operating Capability-Replacement for Radiology. This is the Radiology module of CHCS operating as a stand alone RIS. MDIS shall be interfaced with this system when it is present at the MTF.

Three: CHCS. This is a full DoD hospital information system (HIS) that has the radiology module described in two above. MDIS shall be interfaced with with this system when it is present at the MTF.

5.11.2 Transition Activity Between RIS Approaches.

Successful operation of the MDIS system is contingent upon several processes in addition to the actual imaging functionality. These include entry and use of patient demographic data, order entry functions, and results entry/reporting. In the DoD environment, these capabilities can be provided by the standard systems as described in options Two and Three directly above. Some of the sites may require only the interim RIS solution– i.e option One for the life of the MDIS system. Other larger sites which already have an existing RIS will have it replaced by one of the standard systems at some point during the life of the MDIS. This latter category shall require the interim RIS to be initially responsible for this functionality. Once the DoD standard system is implemented, then the existing interim RIS data shall be converted to be format-compatible with CHCS or CHCS-RAD.

5.11.3. Nature of the RIS Interface.

The actual interface between the RIS and the MDIS system shall be accomplished in a uni-directional or bi-directional manner for actual data transfer. As a minimum, the RIS to MDIS relationship shall be capable of a master to slave relationship for patient data. The MDIS system shall obtain patient demographic data, order entry data, and patient radiology report data from the RIS. If changes to any of these data groups occur within the RIS, the data shall also be immediately updated within the MDIS image database. Redundant manual entry of common data elements in the RIS and the MDIS databases for routine MDIS operations at patient registration points, image acquisition sites, or display workstations is not acceptable.

5.11.4. Use of Autorouting.

A radiology exam order entered in the RIS for a procedure or procedures shall prompt the MDIS image database to do 'autorouting'. The RIS information shall trigger the image database to do autorouting of (a.) exam orders, (b.) pre-interpreted image exams (c.) post-interpreted archived image exams and (d.) radiographic reports, across the MDIS network. This autorouting shall be targeted to specific acquisition and display devices, both in and outside of the radiology department according to site-unique, site definable/modifiable algorithms. Autorouting shall occur when the patient arrives at the radiology department for the examination or be based upon appointment schedules in CHCS or the RIS.

5.11.5. Radiology Diagnostic Reports.

The RIS shall provide patient result entry/reporting capability from the physician workstation area as well as from a transcription area. The reports shall be automatically available with the images in MDIS. Hard copy reports shall be printed automatically upon report approval, upon demand, and/or in batch mode as required at each MTF site.

5.11.6. Information Integrity.

To maintain database consistency between the RIS and MDIS, the following three basic principles shall be observed: use of (a) consistent exam and reporting approach, (b) common data elements, and (c) data elements that are logically compliant with the current ACR-NEMA standards and the proposed ACR-NEMA HIS/RIS/PACS standard.

5.11.6.1. Consistent Exam and Reporting Approach. The radiologic exam philosophy of the MDIS image database shall match that of CHCS (or CHCS-RAD). Radiology orders in both systems shall allow for multiple exams from all modalities. The diagnostic reports shall be linked to each exam associated with the original order.

5.11.6.2. Use of Common Data Elements. The same patient data elements shall be used between the RIS and the MDIS databases.

a. Interim RIS-MDIS Data Elements. Both the interim RIS and MDIS system shall contain the following data elements. These elements shall also be required as the minimum elements needed in both the Interim RIS - MDIS and CHCS - MDIS interfaces. Additionally, any other data elements required to guarantee the information integrity and functionality of

both databases shall be provided. The following are core data elements by system activity that shall be provided:

Core Data Elements Associated by Interim RIS Activity

Activity: Patient Identification/Registration

Patient Name
FMP/SSAN (Unique Patient Identifier)
Date of Birth
Sex
Race
Patient's Home Address/Phone Number
Medical Record Location
Inpatient Register Number
Inpatient Register Number, Suffix (Newborn, AF Only)

Activity: Order Entry/Order Processing

Examination Requested
Procedure Type (Coded)
Clinical Order Comment
Requesting Physician
Unique Examination Identification Number
Exam Priority
Requesting Ward/Clinic
Exam Date/Time
Procedure Location/Modality
Scheduled Date/Time

Activity: Report Processing

Report Text
Report Status (Verified/Unverified)
Reporting Radiologist
Approval Date/Time
Approving Radiologist
Amended Report Text

Amended Report Status
Amended Date/Time
Amending Radiologist

b. MDIS Image Folder Data Elements. The following data elements shall be included, as a minimum, with the images in the patient's electronic folder. These data elements shall also appear at the workstation with the corresponding images. Other data elements required to properly identify the image information and accomplish system functionality shall also be provided. The following are core data elements by system activity for MDIS electronic image folders that shall be provided:

MDIS Image Folder Core Data Elements by Activity

Activity: Patient Identification/Registration

Patient Name
FMP/SSAN (Unique Patient Identifier)
Date of Birth
Sex
Race

Activity: Order Entry/Order Processing

Examination Requested
Clinical Order Comment
Requesting Physician
Unique Examination Identification Number
Exam Priority
Requesting Ward/Clinic
Exam Date/Time
Procedure Location/Modality

Activity: Report Processing

Report Text

Report Status (Verified/Unverified)

Transcribed Date/Time

Reporting Radiologist

Approval Date/Time

Approving Radiologist

Amended Report Text

Amended Report Status

Amended Date/Time

Amending Radiologist

5.11.6.3 ACR-NEMA Compatibility. Any RIS - MDIS interface shall be logically compliant with the current ACR-NEMA standard and the version of the proposed HIS/RIS/PACS standard as of 1 September 1990. This proposed standard is available from NEMA, 2101 L Street, N.W., Washington, D.C. 20037.

6.0 Communications and Network Subsystem.

6.1. General.

Communications entails the physical and logical method of transferring digital images, patient data, and diagnostic reports from point A to point B whether it is intra-MTF, (between departments/clinics/archives), or inter-MTF as in a teleradiology operation. The contractor shall provide communications and network performance as described in this paragraph. This performance applies to large and small MTFs alike.

6.2. Intra-MTF Networking.

The contractor shall use a local area network (LAN) for image management and database management activity. The contractor, at the government's option, shall utilize an existing LAN for all or part of the network solution if it is available and feasible for use in the MTF. This will be determined prior to issuing delivery orders. If the LAN does not meet the throughput or functional requirements, the contractor shall provide the total solution. Throughput requirements outlined in paragraph 8 shall be met. Creation of the LAN in the facility is considered installation activity. (As such, pricing for this activity shall be included in the installation CLINs in section B.)

6.3. Inter-MTF Teleradiology.

The contractor shall provide teleradiology capability between sites as identified by the government. The method is left to the discretion of the contractor but shall meet throughput requirements consistent with specific clinical and operational considerations. The minimum acceptable throughputs shall be site-specific based on imaging department workloads and shall provide transmission of compressed (bit preserved) images, 14 inch x 17 inch, digitized at a nominal resolution of 2K x 2.5K pixels x 10 bits deep. The specific throughputs for low volume and high volume sites are addressed below. Transmission also shall permit unattended, batch capability with an uncorrected error rate of 1 bit in 10^7. Batch transmission shall be interruptible with resumption causing no loss of data. Error detection and recovery shall be without user intervention. Transmission compression (not image compression), when used by the communications protocol, shall be bit preserving.

6.3.1 Inter-MTF Communication.

The contractor shall propose two communication methods between sites that satisfy throughput requirements for low and high volume sites:

6.3.1.1 Low Volume sites. These sites produce images at a nominal rate of 30-100 images per day. The minimum acceptable throughput shall provide complete image set transmission in less than three hours from the start of a batch transmission. The acquired image resolution is as stated above.

6.3.1.2 High volume sites. These sites can be expected to produce 150 images per day. The minimum acceptable throughput shall provide complete image set transmission in less than four hours from the start of a batch transmission. The acquired image resolution is as stated above.

6.3.2 Basic Requirements.

The contractor shall provide and install all applicable hardware/software to support the inter-MTF communications at each site. The contractor shall provide for receipt and transmission of associated clinically significant information (e.g., radiology reports, patient data) to and from the reading MTF and the MTF imaging the patient. A security feature shall be provided to protect patient information by unauthorized users. It will be at the discretion of the government to provide the communications link the contractor proposes. (See paragraph 11.2.8)

6.3.3. Deployable Teleradiology Spoke Option.

As an augmentation to the spoke configurations, a deployable teleradiology capability is required as an option to the spoke capability. This deployable capability shall make use of satellite radio up-links using portable L band radios or their equivalents as the sending communication medium from the spoke. The deployable option provides teleradiology capability where land line communications capability may not be available at the spoke side of the teleradiology link. The digital throughput shall be at least 19.2 kbs with at least 80% communications efficiency. The down link will have images arrive at the hub site through commercially available communications channels. Section J provides additional information on L band uplinks.

6.4. Teleradiology as an Inter-MTF application.

6.4.1. General.

The specific purpose of this capability is to provide primary interpretation capability for radiologic exams acquired at MTFs without assigned radiologists. Specially configured teleradiology equipment may be proposed to accomplish this function. The specifications for these items are described in this and part III of this document. The concept allows for central reading MTFs (hubs) staffed by radiologists to read digitized images transmitted via dedicated communications links from spoke MTFs. As many as eight spokes can be expected to be serviced by single hub when teleradiology is fully implemented. A regional approach will allow a distributed workload and can accommodate images from any Department of Defense MTF. (See paragraph 8.6 for teleradiology performance characteristics).

6.4.2. Unique Requirements.

The workstations shall possess the following attributes in addition to those in paragraph 8.4:

6.4.2.1 Clinical workstation: (This workstation shall be utilized in conjunction with a film digitizer at a spoke MTF.) The clinical workstation shall have sufficient local storage to hold 150 14" x 17" images, digitized at 2K x 2.5K pixels x 10 bits deep.

6.4.2.2. Diagnostic workstation: This workstation, used at the central reading MTF, shall have sufficient local storage to store batched, unattended image transmissions, as described in paragraph 6.3, from multiple spoke MTFs. The spoke MTFs can be expected to transmit from 50 (small site) - 350 (larger site) images at resolutions described in paragraph 6.3 per 24 hour period.

6.4.3.3 Archiving: At the diagnostic workstation site (hub), archiving shall provide storage for at least two years of acquired images. Archiving solutions shall be modular, expandable, and upgradeable.

6.5. Portable Teleradiology:

In addition to the inter-MTF communications links, the contractor shall propose a system for local access to the MDIS via voice-grade phone lines. Access to the MDIS shall permit images and other data to be sent to a workstation (which is connected via phone line) for local display and storage. The intent of this aspect of teleradiology is to allow remote MDIS access for radiologists on-call. The portable package shall weigh less than 50 pounds and shall have a resolution comparable to that of a clinical workstation. Screen size may be less than 19 inches. This system shall support a minimum signaling rate of 19.2 K baud. A security mechanism for protection of these dial-up lines from unauthorized access shall also be a part of the proposal.

Part III. - MDIS System Integration.

7.0 MDIS System Operations.

7.1. General.

The MDIS system shall be a functional single entity that provides radiologic image and data management support within an MTF or between supporting and supported MTFs. While performance of each MDIS component and subsystem is important, the integrated performance of the entire system is the most meaningful measure of clinical acceptability in providing a quality patient care solution. The design philosophy shall encompass a "whole is more than the sum of the parts" approach. The contractor shall provide a system that performs to the parameters specified in the paragraphs below.

7.2. Operational Scenario.

The MDIS system shall support the following operational scenario for radiologic practice.

7.2.1. Image Acquisition and Routing Activity.

7.2.1.1. Image Exam Orders. Exams are ordered in the CHCS system environment. This order entry information is sent to MDIS through the CHCS-MDIS interface. In the absence of CHCS or CHCS-Rad, the radiology information system (RIS) functions of the MDIS system or the contractor-supplied RIS shall provide these functions. The MDIS system shall check its database for previous exams and, if appropriate, they are automatically restored from the long-term archive to the short-term storage for autorouting to the primary reading diagnostic workstation.

7.2.1.2. Network Routing. When a patient reports to the radiology department for an exam, a radiology technologist logs the order request data on the MDIS network and verifies the accuracy. Since the patient demographics and particulars of the radiologic exam order will be transmitted from CHCS to MDIS automatically, this verification action shall require a minimum of typing (patient name or medical record number), barcode reading or equivalent. If information, such as examination type, is incorrect, the technologist will correct it at this time. This process shall require a minimum of manual operations with no redundant entry. The new radiology exams are acquired and following an image quality control check at the image acquisition site, the image or examination is presented to the network. These images and associated data shall be routed on the network to the database storage. They shall then be available on short-term or workstation local storage for viewing at appropriate workstations. As

an occasional alternative, it shall be possible to specially route images to a film printer for hard copy printing.

7.2.1.3. Inter-Workstation Routing. The network shall support routing of images from one workstation to a selected second workstation (diagnostic or clinical for either workstation) at the request of the sending workstation user.

7.2.2. Diagnostic Workstation Activity.

7.2.2.1. Image Presentation. Diagnostic workstation storage receives images and text from image storage or directly from imaging devices. By the time a radiologist goes to a workstation for a clinical session, all the necessary images shall be pre-loaded in workstation local storage. Based on the preselected protocol, the worklist of images shall be presented to the users for diagnosis and review. In some cases– e.g., emergency exams– images shall be immediately routed so that they are available at a particular workstation or hardcopy device as they are produced. The selection and presentation variables are orientation of image, display order by image modality, time of image acquisition, and image acquisition parameters.

7.2.2.2 Image Interpretation. The radiologist selects exams from the worklist and performs interpretation. The required method of operation is to have the worklist updated automatically with new images. Associated images and reports from previous exams are available on the workstation for review with the new examination. Reports are dictated at the workstation and transcribed into the RIS. Subsequently, the reports are introduced into the MDIS system along with appropriate patient data elements so that they are logically matched with the examinations in the patient image exam folder. If a report has been received by MDIS from the RIS, it shall be displayed when the corresponding examination is displayed.

7.2.2.3. Purging Images. Upon completion of the review, following the user-set protocol (time delay, discharge, report availability, and others) the images or exams are automatically purged from the local workstation storage on a first-in first-out or FIFO basis to make room for additional follow-on exams. At the workstation, it shall also be possible to "operator protect" some images or examinations from such automatic deletion.

7.2.2.4. On-demand Queries. Images that are in the short-term storage (STS) or long-term archive (LTA) shall also be viewed on demand, however longer retrieval times as described in paragraph 8 below are acceptable.

7.2.3. Clinical Workstation Activity.

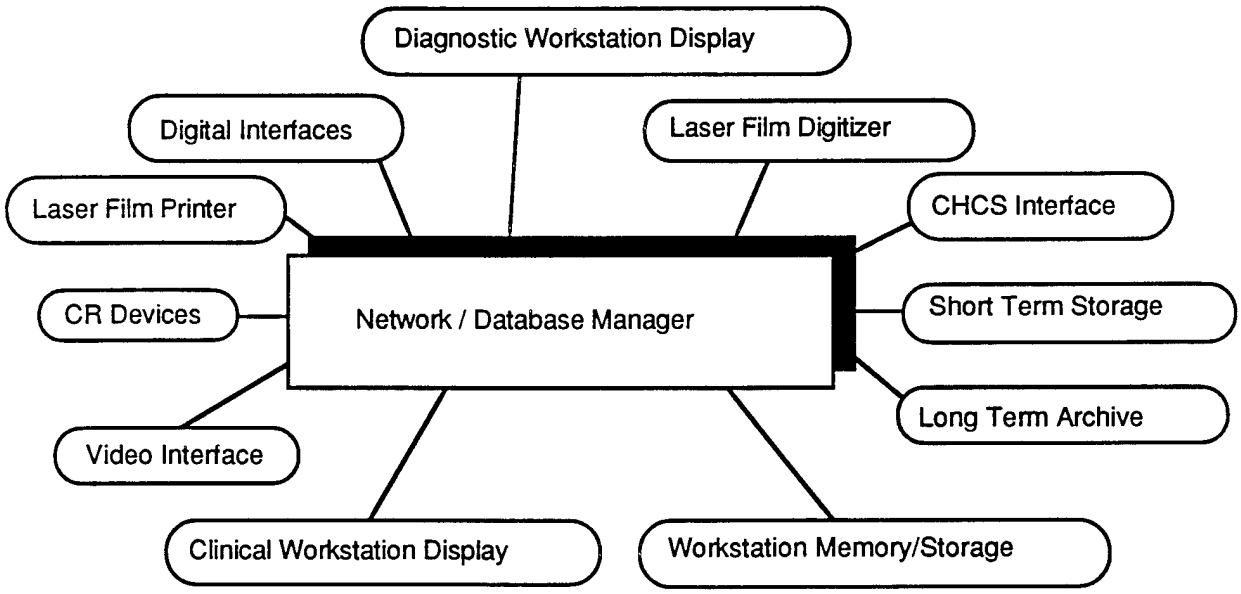
The database autoroutes downsampled radiographic and other digital images (i.e.,CT, MR, US, etc.) and exams to appropriately identified clinical review workstations located throughout the MTF. Short-term storage and/or local workstation storage holds images which are available for review at the clinical workstation. A local list of available images shall be present. On an hourly basis or as expedited for emergencies, autorouted images shall be available at the workstation based on: (1) CHCS appointment schedules or (2) radiologic exam orders placed by the referring physician. Additionally, on-demand interrogations of STS or LTA to retrieve images to a particular workstation shall be possible.

7.3. Network Environment.

7.3.1. Generic Network Configuration.

The contractor shall provide a specific MDIS system solution that meets the generic system solution indicated in the diagram below. The emphasis is on efficient image and patient data flow without regard to specifying any particular topology. Specifically, the diagram below does not imply that a star configuration is required. Any system solution is acceptable as long as it meets performance requirements described in this document. The figure below indicates a generic configuration from a functional perspective.

Figure 7.1 Generic MDIS System, Performance Perspective



7.3.2. Worst Case & Peak Performance Parameters.

Worst case performance shall deteriorate by no more than a factor of 3 compared to the peak performance values. The worst case situation is defined as the transient activity period during which all the imaging systems and workstations are in full clinical operation at the busiest two hours of the clinical day at each site. This is termed a "loaded network condition" for the purposes of evaluation. Peak performance values shall be provided at times other than a loaded network condition.

7.4. System Integration.

The contractor shall provide the MDIS network design and all system integration details. This includes, but is not limited to, meeting the appropriate image quality, data volume, and traffic patterns which provide for establishment of priorities, network data contention resolution, autorouting, and preservation of data integrity necessary to meet performance parameters as specified in this document.

7.4.1 Imaging Systems.

Images are acquired at various imaging modalities such as CR, MR, CT, ultrasound, nuclear medicine, and others. Once the images are acquired and processed by the acquisition device, they shall be automatically transferred to and received by the MDIS network, when appropriate. Some clinical imaging operations (e.g., ultrasound) may require that images be transferred to the MDIS network on an image-by-image basis as selected by the acquisition device technologist. In this situation, the entry of patient name and other demographic data shall be done only once at the image acquisition system. Dual entry of such data into the MDIS system and CHCS (or the RIS) is not acceptable. The data transfer across the interface to the MDIS network shall not impede the operations of the imaging device. Implementation of a full digital interface is required for all digital imaging systems (as described below). For ultrasound imaging devices which do not support a digital interface, digitized video at 512 x 512 x 8 bits is the minimum acceptable image data set.

7.4.1.1. Digital Interfaces. A number of digital imaging devices are in existence at each site– as described in section J-7 for each of the initial MDIS sites. Some devices will have ACR/NEMA interfaces and others may require retrofit interfaces. This will be determined prior to issuing delivery orders. The contractor shall install digital interfaces to all digital imaging systems identified for the MDIS network. These interfaces shall be 'ACR-NEMA compliant' or 'ACR-NEMA equivalent' as elaborated on below. The throughput of the MDIS side of a digital interface shall be equal to or greater than that of the imaging system side. Additionally, the MDIS system shall preserve full acquired image fidelity for interpretation as well as the associated patient and supplemental image data describing the imaging parameters.

7.4.1.2. CR and Film Digitizer Interfaces. The MDIS shall have ACR/NEMA compliant interfaces to the CR and film digitizer.

7.4.1.3. Digital video interfaces.* Ultrasound and some fluoroscopy systems readily produce analog video output. Such output, whether 525 lines or greater, is amenable to digitization of the video frame. This method of acquiring image data is acceptable if the imaging equipment does not provide digital image data output. A minimum of 8 bits of digital data shall result from such digitization. The contractor is responsible for determining how patient text data is introduced when video digitization is used.*

7.4.2. ACR/NEMA Standard Interface.

7.4.2.1 ACR-NEMA compliant. This is defined as conforming to all aspects of ACR-NEMA 300.

7.4.2.2 ACR-NEMA logical.* This is defined as employing the full message structure of the ACR-NEMA Standard 300 as above, but operating over alternative hardware. An ACR-NEMA message shall consist of the command and data set as defined in standard ACR-NEMA 300.* For some uses within the MDIS system, the command portion of the message may be unnecessary. In this circumstance, the remaining data structure (i.e.,the data set) shall remain in conformance to the ACR-NEMA definition.

7.4.2.3 MDIS system use of the ACR-NEMA Standard.

a. The MDIS system shall be ACR-NEMA logically compatible across all digital interfaces (i.e.,the ACR-NEMA message or data set structure shall be used as the MDIS interface data structure). This does not preclude the use of ACR-NEMA compliant interfaces. The preferred internal (internal is defined as within the MDIS network) format is also that of the ACR-NEMA data set, but it may be contractor-specific. If the ACR-NEMA data structure is not used internally, the contractor shall be able to convert his internal format to the ACR-NEMA format for interfaces.

b. Fully compliant ACR-NEMA interfaces shall be used to connect the MDIS to all existing MTF digital imaging equipment for which interface hardware and support software are available as offered by the device provider or third party supplier.

c. If an ACR-NEMA interface is not available for a piece of existing MTF digital imaging equipment, the contractor shall provide a functionally equivalent digital interface. Such an interface is called an ACR-NEMA equivalent interface for purposes of this document. If an

ACR-NEMA compliant interface becomes available subsequent to installation of a contractor-supplied interface, the government may request replacement of the contractor-supplied interface as part of a Section B, schedule III CLIN item. This replacement will be provided at the cost estimated in Section B, schedule III.

d. Fully compliant ACR-NEMA interfaces shall be used to connect CR devices, film digitizers, and laser film imagers to the MDIS system. A number of laser film imagers may already be in possession at the project sites. The MDIS contractor shall interface these printers to the network as a retrofit action. Sub-paragraphs 7.4.2.3.b. and 7.4.2.3.c. directly above apply to the use of the ACR-NEMA interface in this situation. This will be determined prior to issuing delivery orders.

7.4.3. Data Base System Integration.

The MDIS system database shall be fully integrated into workstation operation. Retrieving studies at the workstation, when done outside the worklist function, shall be transparent to the user. When requested studies are in the long-term archive, the retrieval time may be greater than from the short- term storage. If this is the case, a notice of this increased retrieval time shall be sent to the workstation and displayed. There shall also be an user option to abort the requested function. Autorouting of examinations from the STS, LTA, and image acquisition device to workstations shall be fully supported by the MDIS database.

7.4.4. Inter-MTF Teleradiology Integration.

An inter-MTF teleradiology MDIS system shall be fully compatible to the intra-MTF MDIS system in terms of image quality and database management system. The teleradiology devices shall be interchangeable with MDIS components and subsystems.

8.0 Network Performance.

8.1 General.

Network throughput and system image quality are the two primary performance parameters of an effective MDIS system. Each parameter is affected in part by the volume and complexity of image data, frequency and volume of user requests, the degree of data compression, communication priority parameters, and data access speed of the data storage devices. The performance of the entire network shall be able to support efficient,high quality clinical operations of radiologic service for the MTF. Network performance requirements are described from several perspectives. The vendor shall explicitly describe how each of the requirements are addressed in the proposed system design.

8.2 Standard Image Set for Performance Measurement.

The operational response specifications assumes the following data set in Table 8.1 as a typical radiological study to be viewed at workstations.

Table 8 .1 - Standard Image Set for Benchm

Image Type	Data Set per Image	Compression Type	# of Images per Stu
New Chest	2K x 2.5K x 10 bits	bit preserving	2
Previous Chest Image	"	10:1	6
New CT Study	512 x 512 x 12 bits	bit preserving	50
Previous CT Study	"	bit preserving	50

The standard exam image set consists of two types of exams– chest and CT (or MR). The chest images are obtained from a CR unit. The new exams are routed/managed with only lossless compression and previous studies have been restored from the LTA that uses 10:1 compression for CR and lossless compression for CT images. It should be noted that downsampling fits plain radiographic images into 1 k by 1.2 k by 8 bits data sets for routing to clinical workstations outside of the radiology department.

8.3 Imaging Systems, Performance Perspective.

8.3.1. Unimpeded Transfer.

Upon completion of image acquisition, the MDIS system shall provide a means to direct the images to multiple subsystems on the network. The transfer of images from the imaging system to the MDIS network shall not impede the normal operations of the imaging systems regardless of the network traffic condition (i.e., loaded or otherwise). The image throughput performance of the CR on the network shall be same as CR functioning as an independent device.

8.3.2 Throughput Time.

The contractor shall provide automatic image routing capability such that two newly acquired images from a CR device (2K x 2 .5 K x 10 bits with lossless compression) or 50 images from the CT/MRI device can be sent to and received by storage at a diagnostic workstation within 5 minutes or less after image acquisition is concluded under loaded network conditions. Time begins from the initiation of image transfer at the imaging system to the receipt of the new images at the local storage at the workstation.

8.4. Workstation Performance.

Two categories of workstations are required for MDIS; the diagnostic workstation and the clinical workstation. The operational features are described in the paragraphs above; performance is described below.

8.4.1. Diagnostic Workstation Perspective.

Diagnostic workstation performance features shall be supported by the capabilities of subsystems. Moreover, the workstation features shall be given a appropriately high priority in terms of executing the necessary database commands.

8.4.1.1. Workstation Storage. The local storage at the diagnostic workstation shall be sufficient to store all images, new and old, that are needed for a minimum of one day's work. These are defined in clinical scenarios as a appendix to this section.

8.4.1.2. Autorouting.* In a routine clinical situation, the images (new and relevant previous studies) of scheduled patient cases shall be present at the diagnostic workstation image storage ready for interpretation within 5 minutes after image acquisition. Emergency or "STAT" acquire images shall be present in less than two minutes. Diagnostic workstations

shall receive images in the background without noticeable impediment to the viewing process. *Note that autorouting shall be used in support of examination autorouting consultation. See paragraph 4.4.3.29.*

8.4.1.3. Display Speed.* The following description assumes a four monitor workstation. The same specifications shall apply to the workstations with fewer or more display screens. During a clinical day in a diagnostic image reading environment, the diagnostic workstation shall display on demand a list of patient cases to be read by a radiologist. Once a patient case is selected at the workstation, the first full frame of the new chest images (see table 8.1) shall be displayed within 5 seconds. This is the time measured from the end of patient selection to the end of painting the first images on the monitor. As there is a second new chest image, and 50 new CT images, filling the remaining screens shall be accomplished at no more than 5 seconds per screen. (Time measured from the conclusion of filling of one screen to conclusion of filling of the next screen.) During the next 90 seconds* display of any images from the test set not yet displayed shall also be accomplished within 5 seconds. After this time interval display of any of the test set images (which may reside in the display buffer of equivalent) shall be accomplished within 2 seconds power screen. (Measured from the conclusion of filling of one screen to the conclusion of filling the next.,)*Associated text data shall be displayed within a second after the completion of the image display. Since the standard image set is a multi-modality exam, the workstation shall be capable of displaying new chest images (2 images) and new CT images (50 images) for the first time within 20 seconds of the requesting key stroke equivalent.

8.4.1.4. Viewing Long-term Archived (LTA) Images.* If requested images are on line in the LTA, the set of images (6 chest and 50 CT images) shall be available in the diagnostic workstation for display no longer than the 5 minutes after initiating the request. This timing shall be measured under loaded conditions.*

8.4.1.5. Viewing Short-term Storage (STS) Images. If the standard image set is in STS, the display time shall be less than half that of subparagraph 8.4.1.4 above. This timing shall be measured under loaded network conditions.

8.4.2. Clinical Workstation Perspective.

Clinical workstations are located outside of radiology department in clinic and ward settings for reference and review of diagnostic radiologic images. The contractor shall configure frame buffer size, workstation RAM size, local magnetic storage type and size, and the MDIS system interface to meet these requirements.

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8.4.2.1. Autorouting.* In a ward or clinic intra-MTF situation, downsampled images (both new and relevant previous studies) of scheduled patient cases shall be at the workstation image storage ready for review within 15 minutes after the new exam is acquired. * The relevant previous studies-i.e. the last exam- may be in either STS or LTA. Emergency or 'STAT' acquired images (two 14"x 17" CR acquired images) as described in paragraph 3.1.2. above shall be present in less than 3 minutes. *

8.4.2.2. Clinical Workstation Storage. The clinical workstation storage shall be sufficient to store a minimum of two days of images for all patients in the supported ward or clinical area in which the workstation is located. Individual workstation storage requirements shall be upgradeable.

8.4.2.3. Display Speed. For single or dual screen review workstations, the screen image "paint" time for downsampled studies stored at the workstation shall not exceed 5 seconds for the first chest image of a study and not to exceed 2 seconds for each subsequent image. When a study consists of more images than can be displayed on the workstation monitors, the time to display the next (or previous) set of images shall not exceed 5 seconds per screen.

8.4.2.4. Viewing from STS. When the downsampled standard image set is requested from the short- term storage (STS), the first image of shall be displayed within 5 minutes in a loaded network condition.

8.4.2.5. Viewing from LTA. When the standard image set is requested from the archive, assuming the the image is on-line on a storage medium (e.g., disk is in juke box) , the first image shall be displayed within 10 minutes in a loaded network condition.

8.4.3. Output Device Perspective.

The operations of MDIS system network shall not be impeded by any hard copy devices. The interaction between hard copy device and the network shall be such that it shall queue the image print requests. The hard copy device shall produce hard copy images on single emulsion film at preselected default values or specially processed images in response to requests from an authorized user/workstation. The authorized user/workstation shall be able to direct images to any hard copy printer. The hard copy device shall communicate the operational or service status to the user and network manager. Movement times of images to hard copy devices shall be the same as those for movement times to workstations as described above.

8.5. Network Response.

8.5.1. Responses to Requests.

Most image service requests made from workstations or management terminals will involve movement of patient data. Once a request is made by a user at a workstation, the MDIS system shall notify the requestor the status of a request.

8.5.2. Types of Requests.

The response to these requests are for verification purposes. The success or failure of the following requests that generate image or data transfer shall be indicated to the requestor at his or her workstation location:

imaging device to image database

image database to workstation

workstation to workstation

transfer to a hard copy unit

CHCS or RIS to MDIS system image database

8.5.3. Responses to Database Transfers.

A successful response to a request for data movement to the database shall mean that the database has successfully received the data and is assuming responsibility for it. This will allow the sending device to delete the data from its local data storage.

8.5.4. Warnings for Lengthy Transfers.

A request which will produce a lengthy transfer of longer than 15 seconds (for example; moving an entire set of patient studies) shall warn the user and provide periodic indication that the request is being processed. The system shall provide for an abort operation option during a transfer.

8.6. Inter-MTF Teleradiology Performance.

Teleradiology is a method of providing expert radiology diagnostic and consultation service to a distantly located clinical facility by using digital images, image transmission and text communication capability. Teleradiology is a subset to MDIS systems technology. An inter-MTF teleradiology system shall be technically compatible to MDIS system parameters such that it can exchange full image and text data with an intra-MTF MDIS system.

8.6.1. Teleradiology System Configuration.

A teleradiology system consists of the digital image acquisition (e.g., film digitizer or computed radiography) device, a communication link between a remote site to a central location, and diagnostic reporting capability. The primary throughput of such a network depends on the image and associated text data transmission time, image matrix size (e.g., 2K x 2.5K x 10 bits), data compression (bit preserving), and communication speed.

8.6.2. Acquisition Unit.

The plain radiography image acquisition device shall be able to obtain at 2K x 2.5K x 10 bits of data set per image and associated patient data and transmit the them over a high speed link in a batch mode or single examination mode for emergencies. Other digital devices such as CT shall acquire the full data set for their specific modality.

8.6.3. Reports.

The contractor shall provide a means to communicate diagnostic reports back to the remote site and have the reports printed on paper form.

8.6.4. Workstations.

The performance characteristics of diagnostic and clinical workstations are described in paragraph 8.4.

8.6.5. Communication Requirements.

Communication requirements are driven by the image data volume and individual clinical scenario. This information will be available prior to issuing delivery orders.

8.7. MDIS System Redundancy, Reliability, and Crisis Management.

The MDIS system shall have reasonable redundancy in the network design so that no single point of failure can cause the major breakdown of radiology service. See paragraph 10 for systems maintenance considerations. The MDIS system shall prevent any loss of acquired images and data. If a failure prevents image acquisition, the MDIS system shall provide means to enter the missed images from the imaging equipment at a later time. In case a set of images or single image fails to be transmitted from an imaging system, there shall be a way to identify and restore the missing images. The contractor shall have a system crisis management plan. The plan shall be submitted for review as part of systems proposals. It shall include– but not be limited to– responses to the following failures that require data recovery:

a. Failure of Interface to CR devices.
b. Failure of Interface to Digital Imaging System
c. Failure of Interface to CHCS /RIS
d. Methods to Restore Information Integrity between the CHCS/RIS and MDIS databases
e. Failure of Interface to Hard copy Device
f. Failure of Network at Each Logical Connection
g. Failure of LTA capability
h. Failure of STS capability
i. Failure of Workstations, CR Devices, or other major MDIS components

The crisis plan shall address all categories of failures as described in paragraph 1.3.4.2. above (e.g., hard and soft failures of the system).

8.8 MDIS Image Quality.

Interpretation image quality at the diagnostic displays shall be the full spatial and contrast resolution that was delivered to the network across the image acquisition device interface for new images requiring interpretation. Review image quality at the review work station shall deliver the downsampled data set at the spatial and contrast resolution specified in paragraph 8.3 above.

Part IV. - MDIS System Support.

9.0 Training.

9.1. General.

The contractor shall provide a comprehensive training program to include all instructional materials, initial and refresher training, training schedules, quick reference lists, and training program upgrades. Maintenance training is addressed in paragraph 10.

9.1.1. Instructional Material.

9.1.1.1. General. The contractor shall provide all necessary training materials and equipment for any training course conducted (e.g., instructional texts, audio-visual materials and equipment, workstations, etc.). Each student shall be provided one complete copy of the pertinent materials at the start of the formal training program. This set of materials shall include reference materials guiding the basic procedures for using the MDIS. A complete copy of the training materials shall be retained at the conclusion of training by the responsible MDIS facility trainer for use by MDIS users as reference. All training materials (e.g., instructors' text, audio-visual materials, testing, scoring, quick reference lists and evaluation materials, etc.) shall become the property of the government.

9.1.1.2. Quick Reference Lists (QRLs). Each device shall be provided with a QRL describing basic unit mechanical and software operations. The QRL can be a laminated card for devices without a CRT or pop up screen menu that is called for use consistently with the same keystrokes throughout the system at every CRT.

9.2. Formal Training.

The contractor shall include a formal training program consisting of initial and refresher training, ranging in degree from the fully comprehensive system operation for the frequent user to the basic operation and familiarization for general users. The training structure shall target specific groups of MTF personnel based on the degree of system familiarity necessary for these target groups to operate the system at a skill level sufficient to permit their full functionality at their assigned health care tasks. Training shall include development of a training program through formal instructional systems development. This development effort shall include establishment of training standards detailing tasks and proficiency level, a plan of instruction to achieve proficiency levels, formal lesson plans from which

instructors shall train, instructional materials, training literature, instructional exercises and examples, and testing and performance evaluation materials. Hands-on training experience shall include equipment and software identical to that provided in the actual installation.

9.3. Initial/Refresher Training.

Table 9.1 - Training Table

Type of User	Group Trainin	Individual Training
Frequent	2 hours	2 - 2 hr sessions + 2 hr refresher
Occasional	1 hour	2 hr session + 2 hr refresher
Infrequent	1 hour	1 hr session + 1 hr refresher
Radiology Technician	8 hours	8 hours + 4 hr refresher
Support Staff	8 hours	8 hours*

*The site can send a person(s) to factory training for in-depth coverage of system and network management and maintenance procedures.

Group training shall be accomplished in groups of no more than 10 trainees. Individual training shall be done with no more than three trainees in one group.

9.3.1. Initial/Refresher Training.

The contractor shall conduct initial and refresher training at the individual MTF where MDIS is to be installed. The contractor shall customize training to the specific needs of radiologists, medical staff and other frequent users, radiologic technologists, maintenance technicians, administration, ancillary personnel, and system managers.

9.3.1.1. Frequent User. For radiologists and other frequent clinical users medical staff training may require several hours. In the course of their duties, they will read large volumes of images and shall be trained by the contractor to a high proficiency in all aspects of image manipulation.

9.3.1.2. Occasional Users. The contractor shall train medical staff who occasionally use MDIS to perform basic image display and manipulations.

9.3.1.3. Infrequent Users. The contractor shall train nursing staff, physician extenders, and other infrequent users to operate workstations located in the clinical area in which they normally work. They will perform only basic image display and manipulations.

9.3.1.4. Radiology Technologist Users. The contractor shall train radiology technologist users in the overall operation of the MDIS and with all types of workstations and other system components of the MDIS. Technologists will move images from various imaging modalities to the MDIS, retrieve images from both archival and central storage, and view images during quality control procedures. They will receive operator and user maintenance training on CR, film digitizers, laser printers and other devices.

9.3.1.5. Support Staff Users. The contractor shall train administrative and support staff on all MDIS capabilities, especially those relating to fault diagnosis, maintenance of database and integrity, and performance optimization.

9.4. Training Schedule.

9.4.1. Training Schedule.

The contractor shall provide a schedule for training the MTF staff. The contractor shall conduct training on site at the MTF at the convenience of the government during normal duty hours. The government has the option to request training by the contractor on weekends and evenings with reasonable notice of at least two weeks. At the option of the government, the contractor shall conduct training on a regional basis. The contractor shall integrate the training to coincide with equipment installation so that trained MTF staff are available when the contractor establishes initial operating capability.

9.4.2. Software Demonstration.

The contractor shall provide a site-specific software tutorial with the first deliverable. The government expects this package to permit active simulation of an operational workstation for use in training. This demonstration package shall be provided with the first set of deliverables during the post award period.

9.5. Training Program Upgrades.

The contractor shall provide training to the appropriate target audience when system upgrades occur. This training shall be at the level of quality equal to that of previous implementation program.

10.0 System Reliability and Maintenance.

10.1. System Reliability.

10.1.1 Mean Time Between Failure (MTBF).

The contractor's system shall be bound to the performance prescribed by the MTBF values provided in his proposal..

10.1.2 Fault Tolerance.

10.1.2.1. General. The MDIS system shall incorporate fail-safe back-up mechanisms to ensure MDIS system reliability. The system shall be able to resume a database update or image transfer function without loss of data in spite of an interruption due to hardware failure. The system shall detect any erroneous requests, notify the operator of the unsupported function, and suggest alternative approaches if they exist. The MDIS system shall not malfunction (i.e., crash) when confronted with commands that a particular workstation cannot perform.

10.1.2.2. Use of Uninterruptible Power Supply (UPS) Devices. Where appropriate to guarantee against catastrophic failure and and loss of image exam information, the contractor shall supply a UPS at any site-specific modality or piece of equipment. UPS ratings shall be commensurate with the KVA rating of the specified equipment and provide a minimum of 20 minutes operation.

10.1.3. System and Component Uptime and Downtime.

During the warranty period, the MDIS system shall maintain a total system uptime of 99% monthly, and individual component uptime of 95% monthly. The uptime percentages are based on 16 hour per day two shift operation. Total MDIS system downtime of one percent is based on total hours of system hard failure during the calendar month on the basis of a two shift 16 hour day operation. The component downtime of five percent consists of two factors; planned or scheduled downtime, and unanticipated downtime. Planned or scheduled downtime consists of approved, scheduled maintenance, archiving and other programmed unavailability of a component such as; scheduled installation of software, firmware, or hardware. Planned or scheduled downtime comprises three percent of component downtime, with unanticipated downtime comprised of the remaining two percent. Natural disasters, acts of God, or other causes of system malfunction

beyond control of the MDIS site (i.e.,commercial power failure) will not be counted as system or component downtime.

10.1.4. Warranty Extensions and Removal or Replacement of Equipment.

Failure to maintain system uptime of 99% during any one month of the basic warranty period will result in an extension of the warranty period by one month for the system. Failure to maintain major component uptime of 95% during three consecutive months, or to maintain a component uptime of 80% during any one month of the warranty period will constitute grounds for the removal and replacement at the contractor's expense of the component.

10.1.5. Quality Control (QC) Program.*

The contractor shall provide a comprehensive QC program with each delivered system. As a minimum, the program will include any and all MDIS components (e.g. display devices, CR's, digitizers, hard copy devices, and others) that affect the quality of the diagnostic image, the radiation dose to the patient or staff, and the safety of the patient or staff. The contractor shall provide a formal written procedure tailored to the specific MDIS components installed at each site. The contractor shall provide all equipment necessary to conduct the program, a 1 year supply of expendable materials, and a computer based system to perform data analysis, data storage and produce hard copy reports. The contractor shall provide on-site training for personnel who are responsible to conduct the QC program.

10.2 Maintenance.

The contractor shall provide maintenance support for all components of the system at each site. All service shall be provided by factory trained, English speaking, technically qualified and authorized service personnel. All tools, test equipment, parts, and supplies necessary to maintain all components of the MDIS system shall be the responsibility of the contractor. The contractor shall provide a point of contact (POC) for each site– for both hardware and software maintenance. The site shall be able to contact the POC 24 hours a day by telephone or direct communication.

10.2.1. Service Support.

The size and complexity of the system dictates the level of service support required. The contractor shall submit a maintenance/operation plan–to be reviewed during system submittal– for approval using the following guidance:

10.2.2. Large Facility Support.

At larger, fully integrated (networked) sites, the contractor shall provide on-site technical support for operating and maintaining the system. Such support shall be provided or made available on-site when the contractor establishes IOC and remain accessible on-site during the warranty period, including extensions. On-site technical support shall be available during normal daytime work hours identical to those of the radiology department site where support is provided through this contract. The contractor shall provide information pertinent to work qualifications, experience history, and educational background for each member of the on-site technical support staff. This information should include copies of training certificates, or descriptions of training programs that demonstrate that the staff member possesses credentials, skills and abilities to provide the required functions. On-site technical support shall include skills in system engineering, database management, and technical systems analysis, including repair and maintenance. Typical staff skills required are described below.

10.2.2.1. System Engineer- Responsible for optimal operation of all the computer components of the MDIS system, including databases, image transmission, interfaces, and electronic image archives.

10.2.2.2. Database/Archive Manager- Responsible for all aspects of image archiving, both electronic and hard copy. Assures that imagery is entered into the archive in the correct format and is readily available for physician review and diagnosis. Shall demonstrate competence in the use of computers for data management, and in operation of a medical center image archive system.

10.2.2.3. Computer Technician/Trainer- Responsible for maintenance and training on the system. Shall demonstrate competence in all aspects of computer systems maintenance and have a thorough understanding of electronic circuits and trouble shooting techniques. Shall be proficient in the operation of all components of the system, and fully capable of training others in the proper operation of the equipment.

10.3. Warranty Maintenance.

Contractor shall provide warranty for all parts and labor for 12 months following government acceptance of the MDIS system. Warranty shall include around-the-clock (24 hour) response. The government representative will make formal notification of the problem by phone to the contractor POC. Such notification will cause the response time measurement to commence. During the warranty period, the contractor shall furnish maintenance service support that includes, as a minimum, preventive and corrective maintenance services for the MDIS system and all associated hardware, firmware, and software components and additional accessories ordered with the MDIS system. The contractor shall provide all parts, labor, travel, and expenses necessary to perform such services at no additional cost to the government, except in those circumstances where maintenance or repair service is required as a direct result of abuse, misuse, misconduct, or other gross or willful damage done by the government.

10.3.1. Preventive Maintenance (PM).

The contractor shall perform all PM services required for system hardware, firmware, and software at times convenient to the government. The contractor shall furnish a preventive maintenance plan/schedule for review with system submittal and approval as part of a delivery order. The contractor shall schedule and coordinate PM services and obtain approval of the schedule by the government's representative at the site. PM shall be performed on individual components of the system so as not to affect the operation of the entire system.

10.3.2. Corrective Maintenance.

The contractor shall provide on-site hardware, firmware, and software corrective maintenance service, to include software problem analysis, associated reprogramming, and corrected software documentation. The contractor shall make every effort to effect repairs in the most expedient manner with minimum interruption to the operation of the system.

10.3.3. Response Time.

10.3.3.1 Large Facility. During the warranty period, the contractor shall respond on-site to emergency calls within 2 hours following notification. An emergency call is defined as a hard failure of a component when no back-up is available, or a hard failure of the system that prevents the site from accomplishing its normal workload with the remainder of the system. Included in routine failures are all soft failures and hard failures of a component that has back-up capability. The contractor shall respond on-site to routine calls within 12 hours following notification by the government representative.

10.3.3.2. Small Facility/Teleradiology Sites. During the warranty period, the contractor shall respond on-site to emergency calls during the same day or within four working hours, based on an eight hour work day that ends at 1700 hours. Response to routine calls shall be within the next work day. Emergency and routine calls as defined above also apply to the small facility/teleradiology.

10.3.4. Reports of Service.

All reports of service (preventative maintenance or repair) shall be documented and provided to the appropriate on-site government representative and filed with the equipment history file. As a minimum, the report shall include: (a.) date and time notified, (b.) date and time of arrival on-site, (c.) description of malfunction or service to be performed, (d.) model number/serial number and location of the equipment, (e.) time spent to repair, (f.) parts used/replaced, and (g.) description of service performed.

10.3.5. Software, Firmware, and Hardware Support.

10.3.5.1. Commercially Available Upgrades. See Section H.

10.2.5.2. Newly Developed Components. See Section H.

10.3.5.3. Participation In User Groups. If the contractor supports a customer user group as a technique to develop, maintain or show system improvements via software system change requests (SCRs), each individual military site will be granted user-group membership status. Military sites will be granted up to 9 priority SCRs each year. These priority change requests will have precedence over all other categories and priorities of user changes evolving from the customer user groups. These nine government user SCRs shall receive the highest priority consideration for system improvements under the same terms and conditions of the operating charter of the user group. If systems changes are offered through the user group at no cost to the customer, then the government users under this acquisition shall benefit from this stipulation.

10.4. Maintenance.

10.4.1. General.

The contractor shall provide a maintenance program for each system provided, for up to 8 years following conclusion of the one year warranty. The scope of the services provided and the requirements for system reliability shall be the same as required during the warranty period and

includes all parts, labor, system hardware, firmware, and software changes and periodic user training.

10.4.2. Maintenance Years.

Each annual maintenance year may be ordered by the government up to thirty days after the end of the warranty period for the first year, and up to thirty days after the end of the previous year's maintenance program for year's two through eight. If a maintenance year is not ordered for a specific system, phase or component, then all subsequent years are null and void for that system, phase or component.

10.5. Support Personnel.

10.5.1. General.

Individual technical staff shall be committed for the full duration of the systems development effort. On site at each MTF shall also be committed for the full duration of the warranty and/or annual maintenance period. These personnel shall be qualified with extensive and demonstrated experience in related work. A resume will be provided to document support personnel qualifications.

10.5.2. Designation of Key Personnel.

The contractor shall include among the personnel to be assigned to perform under this contract certain individuals designated and clearly identified to the government as key personnel. The personnel so identified shall be considered essential to the work described herein. The project manager is crucial to the success of this effort. He shall have successfully managed projects of this type, magnitude, and complexity within the past three years. Prior to directing any of the specified key personnel to other programs, the contractor shall provide advance written notification at least 15 calendar days to the Contracting Officer and shall submit justification (including proposed substitutions with resumes) in sufficient detail to permit evaluation of the impact of the proposed change on the program and its schedule. No diversion shall be made by the contractor without the written consent of the Contracting Officer.

10.5.3. Replacement of Unsatisfactory Personnel.

In the event the contractor personnel's performance is unsatisfactory to the government, the Contracting Officer reserves the right to request and receive satisfactory personnel replacement on a timely basis.

11.0 Complete Installation.

11.1. General Requirements.

11.1.1. Standard Products.

Material and equipment to be provided shall be the standard products of manufacturers regularly engaged in the manufacture of the products. Products and components out of production at the time a delivery order is written are not acceptable.

11.1.2. Dataplates.

Major components of equipment shall have the manufacturer's name, address, type or style, component serial number and catalog/model number on a noncorrosive and non-heat sensitive plate which is securely attached to the equipment.

11.1.3. Full Installation.

The contractor shall be responsible for determination of, and compliance with Federal and state or local code requirements, design data, and other factors necessary to design and install the system at each location. All items of work not detailed in this specification and all data not furnished by the government, but required by the contractor for complete system installation, are the responsibility of the contractor to request and obtain. Approval for the contractor to proceed with installation of the MDIS System shall be contingent upon the government's approval of design submittals and written notification to proceed with installation.

11.1.4. Installation Requirements.

11.1.4.1 Rigging: The contractor shall be responsible for the safe, physical movement of equipment from the delivery point at the final destination, to the area of installation and uncrating of the equipment.

11.1.4.2 Removal: The contractor shall remove rubbish and debris from the site daily, unless otherwise directed. Burning is not acceptable. The contractor shall store all materials which cannot be removed daily, in an area specified by the contracting officer.

11.1.4.3. Damages: All existing structures damaged or defaced as a result of the contractor's installation work shall be restored by the contractor, as directed and approved by the contracting officer, at no additional cost to the government.

11.1.4.4. Existing Utilities: The contractor shall check and verify the location of existing utilities required to remain in place and in service, and those designated to be relocated or removed. The contractor shall be responsible to protect, maintain, remove and/or cap utilities as necessary, in accordance with local codes and regulations.

11.1.4.5. Utility Connections: The contractor shall connect to designated utilities in a manner conforming to a nationally recognized code which addresses the specific utility, and at a time satisfactory to minimize or preclude disruption to existing functions or clinical services. The contractor shall provide at least two days (48 hours) notice to the contracting officer's on-site representative -prior to making any tie-ins.

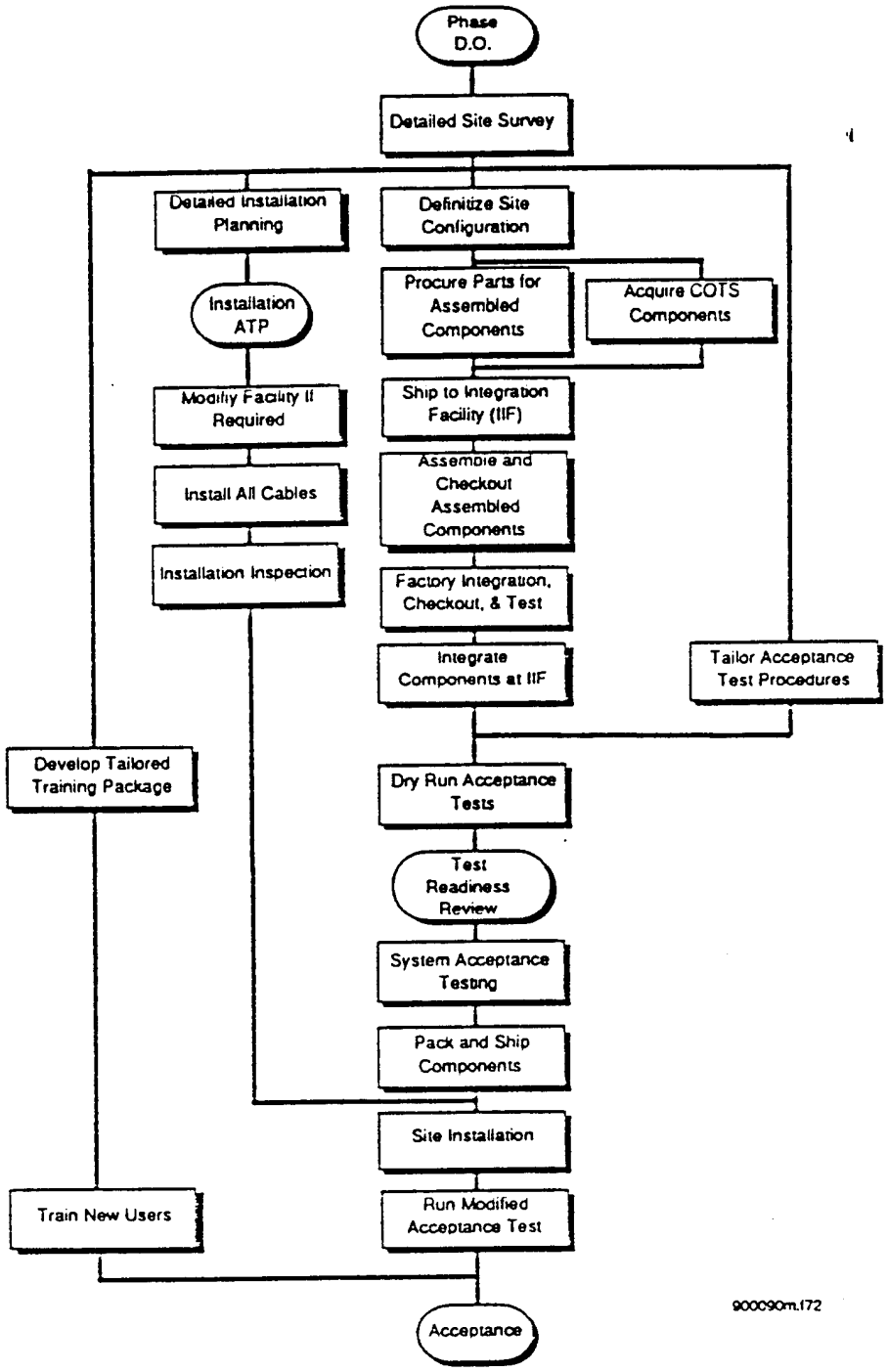
11.1.5. Installation Data Submittals.

See Sections F and J.

11.2. Turn Key Installation.

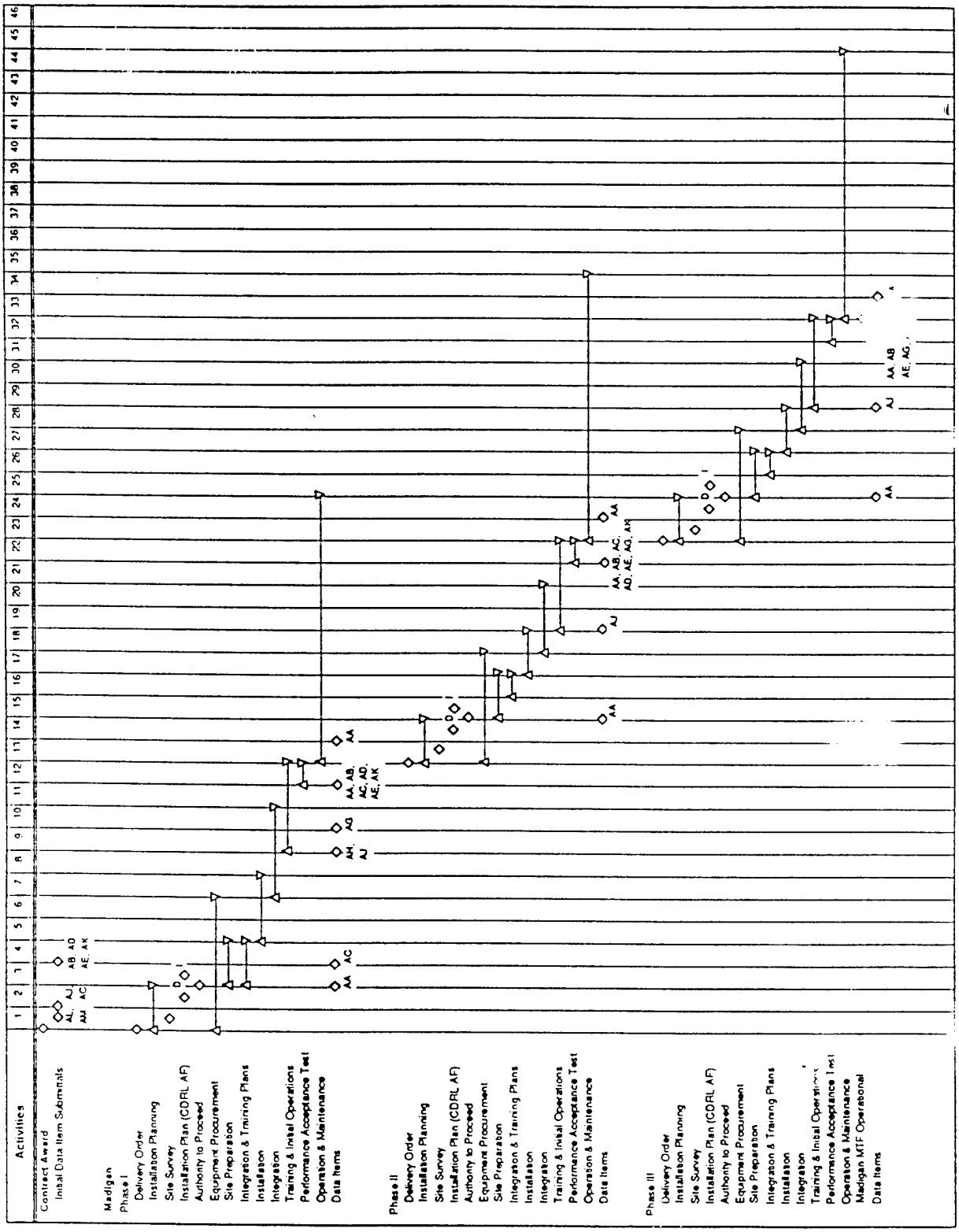
The contractor shall propose complete, fully operational installation of the system "turn-key". The contractor shall provide to the government "blue line" drawings and accompanying fully descriptive text. These documents shall fully define and illustrate all proposed changes to heating, ventilation, (e.g., air exchanges, etc.) and air conditioning systems (e.g., loads, designed/rated operation of all computer equipment, etc.); utility connections, chases and conduits to include communications; room illumination; plumbing; drains; improvement to floor loading capacities; penetrations of fire and load bearing walls and finished floors; and other changes to the characteristics of the existing physical plant necessary for the contractor to install a fully operational system. The contractor shall assess and describe the requirements for egress and passage of equipment through facility doorways and corridors and if required, elevators to the installation sites. The description shall include an assessment of door widths and heights and dynamic and static distributed point loads of the equipment and certification that equipment the contractor proposes to install can pass safely and easily to all installation locations. All equipment supplied shall be able to fit through standard hospital doors and elevators with little or no modification to the physical structure. If the physical structure must be modified to permit transport of the equipment to the installation site, the contractor shall be fully responsible for the modifications and for restoring the modifications to their original condition at no additional cost to the government.

APPENDIX B: MDIS IMPLEMENTATION PROCESS MODEL



Loral/Siemens phase implementation process model

MADIGAN MDIS PROGRAM SCHEDULE



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